

Multistate Outbreak Investigation of Multi-Serotype *Salmonella* Associated with Cashew Brie April to July 2021

Final Report

April 2023

Prepared by Ken Zamora
California Department of Public Health
Food and Drug Branch
Emergency Response Unit

California Department of Public Health
Food and Drug Branch
P.O. Box 997435, MS 7602
Sacramento, CA 95899

Table of Contents

Agencies Involved	2
Dates of Investigation	2
Executive Summary.....	2
Background	4
Inspection and Environmental Assessment.....	4
Laboratory results	6
Recall	6
Summary of Outbreak Investigation Findings	7
Attachments.....	7
Exhibits	8

Agencies Involved

California Department of Public Health (CDPH), Food and Drug Branch (FDB), Emergency Response Unit (ERU)

CDPH, Food and Drug Laboratory Branch (FDLB)

United States Centers for Disease Control and Prevention (CDC)

United States Food and Drug Administration (FDA).

Dates of Investigation

April 2021 – July 2021

Executive Summary

Beginning on April 15, 2021, the California Department of Public Health (CDPH) Food and Drug Branch (FDB), participated in a multistate outbreak investigation of multi-serotype *Salmonella* linked to the consumption of cashew spread manufactured and distributed by Jule's Foods in Carlsbad, CA.

Outbreak cluster code 2014MLDS-1 consisted of 20 Salmonellosis cases in 4 states. This outbreak included people infected with one of four *Salmonella* serotypes: Chester, Duisburg, Typhimurium, and Urbana. Fifteen cases were in California, two in Tennessee, two in Florida, and one in Maryland. Known illness onset dates ranged from 12/11/2020 to 5/9/2021. Ages ranged from 1 to 72, with a median age of 26 years old, 65% were female. Five people were hospitalized, and no deaths were reported. State and local public health officials interviewed people about the foods they ate in the week prior to becoming sick, and 15 (75%) reported eating Jule's Foods Cashew Brie.

On April 15, 2021, CDPH staff collected seven retail samples of Jule's Cashew Brie: Jule's Classic Cashew Brie, Jule's Truffle Brie, and Jule's Black Garlic Brie. Samples were collected from the Davis Food Co-op in Davis, CA and the Juice Shop in Corte Madera, CA. The samples were hand delivered by CDPH staff to CDPH Food and Drug Laboratory Branch (FDLB) in Richmond, CA for testing. Six of the seven samples collected would later be reported positive for *Salmonella*.

On April 21, 2021, CDPH staff assisted U.S. Food and Drug Administration (FDA) in the Preventive Controls (PC) inspection and collection of environmental and food samples at the Jule's Foods manufacturing facility, where samples of [REDACTED] were collected and found to be [REDACTED]. [REDACTED] GC 7927.705 - 21 CFR

On April 22, 2021, Jule's Foods issued a voluntary recall on all lots of all products manufactured by the firm, due to the potential contamination with *Salmonella*.

On April 29, 2021, CDPH embargoed all organic blanched cashew kernels held by Jule's Foods. On May 25, 2021, 10 boxes of 100% organic blanched cashew kernels were voluntarily destroyed by the firm.

On May 5, 2021, CDPH staff collected a left-over sample of Jule's Classic Cashew Brie from a case patient's home in [REDACTED], CA. CDPH-FDLB isolated *Salmonella enterica* serotype Urbana from the left-over sample.

On October 18, 2021, Jule's Foods paid a civil penalty of \$7,500 for producing and distributing adulterated food.

Background

Beginning on April 15, 2021, CDPH FDB, participated in a multistate outbreak investigation of multi-serotype *Salmonella* (U.S. Centers for Disease Control and Prevention (CDC) cluster code 2104MLDUS-1) linked to the consumption of cashew spread manufactured and distributed by Jule's Foods in Carlsbad, CA. The firm had a Processed Food Registration (PFR #104138) and Organic Processed Product Registration (OPPR #104138) with the state of California. At the time, CDC data for the outbreak strain of *Salmonella* Duisburg 2104MLDUS-1, identified five case patients with illness onset dates ranging from February 1, 2021 to February 27, 2021. All isolates were genetically indistinguishable. Commonly reported grocery stores included: Whole Foods (4), Ralphs (2), Sprouts (2), and Trader Joes (2). Three patients reported a mainly vegetarian or vegan diet. Two patients reported eating meat alternative nuggets. Three patients reported consuming Jule's Vegan Truffle Cashew Brie.

Outbreak cluster code 2014MLDS-1 eventually expanded to include twenty Salmonellosis cases in four states. This outbreak included people infected with one of four *Salmonella* serotypes: Chester, Duisburg, Typhimurium, and Urbana. Fifteen cases were in California, two in Tennessee, two in Florida, and one in Maryland. Known illness onset dates ranged from December 11, 2020 to May 9, 2021. Ages ranged from 1 to 72, with a median age of 26 years old, 65% were female. Five people were hospitalized, and no deaths were reported. State and local public health officials interviewed people about the foods they ate in the week prior to becoming sick, and fifteen (75%) reported eating Jule's Foods Cashew Brie.

Inspection and Environmental Assessment

On April 15, 2021, CDPH staff collected seven retail samples of Jule's Cashew Brie: Jule's Classic Cashew Brie, Jule's Truffle Brie, and Jule's Black Garlic Brie. Samples were collected from the Davis Food Co-op in Davis, CA and the Juice Shop in Corte Madera, CA. (See Exhibit 1 - Evidence Sample Receipts, dated 4/15/21.) The samples were hand delivered by CDPH staff to CDPH Food and Drug Laboratory Branch (FDLB) in Richmond, CA for testing on April 15, 2021.

On April 21, 2021, CDPH staff assisted FDA in the PC inspection and sample collection at the Jule's Foods manufacturing facility located at 2790 Loker Avenue W, #115, Carlsbad, CA 92010. The investigation was led by FDA Consumer Safety Officer (CSO) GC 7927.705 - 21. CDPH Environmental Scientist (ES) Ken Zamora, ES Nik Storm and FDA CSO 7927.705 assisted with the recall discussion, environmental sampling and product sampling conducted on April 21, 2021. All samples collected during the investigation were sent to FDA for analysis. 7927.705

The firm's owner, Jules Van Dam, and Operator, GC described the cashew-based brie manufacturing steps as follows: Cashews are soaked under 7927.605 7927.605 in 7927.605

7927. The cashews are strained and portioned out. The cashews are blended then transferred to a container to ferment for 7927.6. The product is transferred to a 7927.605 and 7927. for approximately ^{(GC) 7927.605 - Trade Secret}. The product is transferred to a box, salted, and allowed to sit for 7 GC 7927.605 - . The product is then packaged and labeled.

FDA personnel continued the PC inspection and sample collections at Jule's Foods manufacturing facility until May 24, 2021. GC 7927.705 - 21 CFR 20.88 - FDA

[REDACTED]

On April 29, 2021, CDPH investigator Maria Gliaudys conducted a follow up investigation and met with Ms. Van Dam and 7927.70 at Jule's Foods' processing facility. Investigator Gliaudys issued an embargo pursuant to California Health and Safety Code Section 111860 on 12 boxes, 50-70 pounds each, of 100% Organic Blanched Cashew Kernels. These products were placed under embargo at Jule's Foods' processing facility in Carlsbad, CA. The firm was also issued a Notice of Violation (NOV) for warehousing adulterated food (organic blanched cashew kernels). Investigator Gliaudys also observed the firm's Voluntary Condemnation and Destruction (VC&D) of all cashew brie product being held on site. (See Attachment 4 - CDPH Food Activity Compliance Tracking Form.)

On April 30, 2021, FDA's CORE network initiated an on-site record and sample collection at 7927.605 . GC 7927.705 - 21 CFR 20.88 - FDA

This information was provided to Jule's Foods, whose manufacturing process for cashew brie did not control for the microbiological hazard.

On May 5, 2021, CDPH staff collected a left-over sample of Jule's Cashew Brie from a case patient in GC 7927.700 -, CA. (See Exhibit 2 – Evidence Sample Receipt, dated 5/5/21.)

On May 25, 2021, CDPH investigator Scott Stys met with Ms. Van Dam at the firm's facility located at 2790 Loker Ave., #115, Carlsbad, CA 92010 to observe the firm's VC&D of ten boxes of 100% organic blanched cashew kernels. The remaining 2 boxes were donated to the UC Davis Department of Food Science and Technology for food safety research. (See Attachment 5 - CDPH Investigation Report.)

On June 11, 2021, CDPH sent Ms. Van Dam a regulatory letter scheduling a regulatory office meeting for July 14, 2021. (See Attachment 6 – Regulatory Letter.) On September 21, 2021, CDPH sent Ms. Van Dam a Civil Penalty letter (case #21F131001) informing her that CDPH had assessed a civil penalty of \$15,000 for producing and distributing adulterated food and provided the opportunity to meet virtually to discuss the matter on October 12, 2021. (See Attachment 7 - Notice of Violation and Assessment of Civil Penalty Letter.) An agreement was reached with the firm to lower the penalty to \$7,500, provided that payment was made expeditiously and in full. The payment was submitted to CDPH on October 18, 2021.

Laboratory results

On April 21, 2021, the California Department of Public Health – Food and Drug Laboratory Branch (FDLB) reported that *Salmonella* was detected in six of the seven retail samples collected on April 15, 2021. *Salmonella* was detected in the following six samples: IS# 761041521-P001 (Jule’s Truffle Brie), 761041521-P002 (Jule’s Classic Cashew Brie), 761041521-P004 (Jule’s Truffle Brie), 761041521-P005 (Jule’s Truffle Brie), 761041521-P006 (Jule’s Classic Cashew Brie), and 761041521-P007 (Jule’s Black Garlic Brie). Whole Genome Sequencing (WGS) results from FDLB reported the following *Salmonella enterica* serotypes: IS# 761041521-P002 (Urbana), 761041521-P004 (Urbana), 761041521-P005 (Urbana), 761041521-P006 (Chester), and 761041521-P007 (Vinohrady). (See Attachment 2 - CDPH-FDLB - Analyst Sample Description and Summary Report.)

All samples collected at Jule’s Food’s manufacturing facility in Carlsbad, CA on April 21, 2021, were analyzed by FDA laboratories. GC 7927.705 - 21 CFR 20.88 - FDA

[REDACTED] (See Attachment 3 – FDA Establishment Inspection Report.)

On July 27, 2021, CDPH-FDLB reported that they detected *Salmonella enterica* serotype Urbana from the left-over case patient sample (subsamples 707050521-P001A and 707050521-P001B) collected from the home of a case patient living in GC 7927.700 -, CA and a retail sample (subsamples 761041521-P001A and 761041521-P001B) collected from the Davis Food Co-op in Davis, CA.

Recall

During the PC inspection and sample collection on April 21, 2021, a call was held between CDPH, FDA, Ms. Van Dam, and 7927.70. The firm was informed that six of the seven retail samples collected by CDPH on April 15, 2021, were presumptive positive for *Salmonella* (confirmed on April 22, 2021) and included each of the three varieties manufactured by the

firm. Ms. Van Dam stated they had already begun contacting customers to recall their cashew brie products, including all varieties and best by dates, and had been able to inform all but two of their customers. She also stated they would contact the two remaining customers that day to notify them of the product recall. Towards the end of the call, Ms. Van Dam also stated her intention to work with CDPH and FDA to issue a voluntary recall notice.

On April 22, 2021, Jule's Foods issued their press release. (See Attachment 1 – Jule's Food's Recall Press Release.) The firm recalled all lots of all the food products they manufacture: Jule's Cashew Brie (Classic), Jule's Truffle Cashew Brie, Jule's Black Garlic Cashew Brie, Jule's Artichoke Spinach Dip, and Jule's Vegan Ranch Dressing. Additionally, Jule's Foods suspended production of these products while the FDA and CDPH continued their investigation.

Summary of Outbreak Investigation Findings

On April 15, 2021, CDPH collected seven retail samples of Jule's Cashew Brie due to epidemiological data which indicated an association between a multi-state outbreak (CDC cluster code 2104MLDUS-1) and Jule's Foods Cashew Brie. Six of the seven retail samples tested positive for *Salmonella*; serotypes Chester, Urbana and Vinohrady were isolated from the samples. (See Attachment 2 - CDPH-FDLB - Analyst Sample Description and Summary Report.)

In response to the CDPH laboratory results, Jule's Foods initiated a voluntary recall of all products manufactured by the firm and made the decision to halt all production.

Jule's Foods' supplier of 100% organic cashew kernels was identified as [REDACTED] 7927.605 [REDACTED]. The 100% organic cashew kernels supplied by [REDACTED] 7927.605 [REDACTED] are sold GC 7927.705 - 21 CFR 20.88 - [REDACTED]. (See Exhibit 4 - Product Specification Sheet - Organic Cashew Small Pieces OSWP.) Jule's Foods did not have a control in place for the microbiological hazard. Jule's Foods was determined to be responsible for the multistate outbreak of multi-serotype *Salmonella* (Outbreak cluster code 2014MLDS-1) and paid a civil penalty of \$7,500 for manufacturing, warehousing and distributing adulterated food to the public.

Attachments

- Attachment 1 - Jule's Food's Recall Press Release.
- Attachment 2 - CDPH-FDLB - Analyst Sample Description and Summary Report.
- Attachment 3 - FDA Establishment Inspection Report.
- Attachment 4 - CDPH Food Activity Compliance Tracking Form.
- Attachment 5 - CDPH Investigation Report.
- Attachment 6 - Regulatory Letter.
- Attachment 7 - Notice of Violation and Assessment of Civil Penalty Letter.

Exhibits

- Exhibit 1 - Evidence Sample Receipts, dated 4/15/21.
- Exhibit 2 - Evidence Sample Receipt, dated 5/5/21.
- Exhibit 3 - **GC 7927.705 - 21 CFR 20.88 - FDA**
- Exhibit 4 - Product Specification Sheet - Organic Cashew Small Pieces OSWP.