

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

Incident Name: *Salmonella* Senftenberg
/Peanut Butter/May 2022

2. Operational Period: Date From: 6/17/2022 Date To: 7/8/2022
Time From: 1100 ET Time To: 1100 ET

3. Objective(s):

(b) (5)

4. Operational Period Command Emphasis:

General Situational Awareness:

Operational Period #1: As of 5/24/2022, there are 16 cases from 12 states: AR, GA (2), IL, MA, MO (2), NC (2), NY, OH, SC, TX (2), VA, WA. Cases are highly related by 0-5 SNPs (avg 1). Surrounding the cluster, as identified by the [NCBI tree](#), there are several peanut butter isolates collected at a KY peanut butter processing facility between 2014 and 2017. These isolates are related to the clinical cases by 0-14 SNPs (avg 4). Isolation dates for this cluster range from 2/20/2022 - 4/24/2022. There have been two hospitalizations and no reported deaths. CDC has limited exposure information reported, however, with 4/5 cases reporting peanut butter, and 3/4 specifically reporting JIF brand. On 5/19/2022, HAF 5E along with state partners from KY initiated an inspection at JM Smucker LLC (Lexington, KY); an assignment for full scope PC inspection with environmental sampling (eNSpect #224229) was later issued. The firm is providing requested records to the investigators regarding environmental monitoring result, among other information requested. On 5/19/2022, CDC held a states call to gather additional epidemiologic information. On the call, it was shared that five of five cases specifically asked report peanut butter consumption. Four cases provided brand information that they consumed Jif (two Natural, one Reduced Fat, one Jif with no further variety information). The fifth case did not provide brand information. A focused questionnaire will be deployed to the states to re-interview. On 5/19/2022, CORE and HAF 5E coordinated a firm call with JM Smucker and representatives from (b)(4). Information related to the epidemiology was shared by CDC and FDA shared what is known regarding the WGS of the 2010 isolate. All Natural and Reduced Fat peanut butter at this plant is manufactured on line (b)(4). On 5/20/2022, CORE and HAF 5E coordinated a firm call with J.M. Smucker Company and representatives from (b)(4). The firm explained a timeline of positives found in their firm and with respect to the installation of (b)(4). They agreed to a voluntary recall. On 5/20/2022, J.M. Smucker Company issued a voluntary recall for products manufactured at the Lexington, KY facility manufactured (b)(4). On 5/20/2022, CORE issued a webpost regarding the outbreak and associated recall. This webpost was minorly updated on 5/21/2022, 5/22/2022, and 5/23/2022 to include updated product recall information. On 5/21/2022, CDC issued a webpost regarding the outbreak and associated recall. On 5/20/2022, HAF 5E collected 206 environmental swabs at J.M. Smucker Company in Lexington, KY (Sample #1139991). These were shipped for Saturday Delivery to NFFL for *Salmonella* analysis. On 5/23/2022, ORA/ORS notified CORE that 27 of the 206 subs were negative for *Salmonella*, with the balance pending. On 5/23/2022, ORA HAF 5E (CIN-DO) provide photo of the product consumed by the OH case. The lot code is 20174250202:30 with best if used by date Jan 17, 2023, which is included in the recall and manufactured at the Lexington, KY facility on (b)(4). ODH is planning on analyzing this product for *Salmonella*. On 5/23/2022, CDC alerted CORE of an additional case in this cluster from MO. This case had exposure to recalled Jif peanut butter. On 5/23/2022, Shopper card records from a VA case showed five purchases of Reduced Fat Jif peanut butter in late Jan and throughout Feb 2022. On 5/23/2022, FDA received media inquiries from Food Safety News and Washington Post. On 5/23/2022, received inquiry from INFOSAN related to international distribution. Customer information provided by J.M. Smucker on 5/23/2022 shows: Canada, Dominican Republic, Singapore, Malaysia, Taiwan, South Korea, Thailand, Japan, Spain and Honduras. INFOSAN is aware of international distribution to Canada, Israel, Hong Kong, and Saudi Arabia.

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Operational Period #2: As of 6/1/2022, there are 16 cases from 12 states: AR, GA (2), IL, MA, MO (2), NC (2), NY, OH, SC, TX (2), VA, WA. As of 6/1/2022, CDC shared available exposure information for 11 patients. Of 11 patients with brand information, 11 (100%) report Jif brand peanut butter of various types. On 5/24/2022, ORA/ORS notified CORE that two of the environmental swab sub samples from Sample #1139991 were Cannot Rule Out (CRO) for *Salmonella*. On 5/24/2022, CORE held Tactics Call #1. The corresponding Operational Briefing shared contained a summary of the situational awareness, objectives in place, and sampling guidance for FDA and state partners. On 5/24/2022, CDC notified CORE of an additional case from NC. Additional epi information for this case is pending. On 5/24/2022, CORE coordinated a Special Purpose Tactics Call (SPTC) for discussion between CFSAN and HAF 5E regarding the investigation at J.M. Smucker in Lexington, KY. On 5/24/2022, HAF 3W (DAL) alerted CORE that TX DSHS collected a case-associated sample of Jif with lot number 2024 425 01 13:26 for *Salmonella* analysis. On 5/25/2022, CORE and HAF 5E (CIN) coordinated a firm call with J.M. Smucker to discuss their root cause investigation. On 5/25/2022, NY DOH collected two jars leftover from a NY case included in the outbreak for *Salmonella* analysis. The jar consumed prior to symptom onset has a lot code of 20174250205:34 and the additional jar has a lot code of 2033006111256. As of 5/25/2022, CDC shared available exposure information for 10 patients. All reported eating peanut butter. Of nine patients with brand information, nine (100%) report Jif brand peanut butter of various types: creamy, natural creamy, creamy reduced fat, and natural creamy low sodium. On 5/26/2022, updated the case count on the a [webpost](#) regarding the outbreak and associated recall. On 5/27/2022, CFSAN/OAO provided a summary of 1046 CAERS reports related to Jif peanut butter. On 5/27/2022, OC/OEM provided a summary of 219 consumer complaints submitted to coordinators regarding Jif peanut butter. On 5/27/2022, HAF 5E provided the Corrective Actions and Restart plan that was submitted by J.M. Smucker for review. On 5/31/2022, Ohio Department of Health (ODH) reported the leftover Jif peanut butter from the OH case tested negative for *Salmonella*. On 5/31/2022, ORA ORS reported the 206 environmental swabs collected at J.M. Smucker Company in Lexington, KY (Sample #1139991) have tested negative for *Salmonella*. On 5/31/2022, CFSAN/OAO provided a summary of 1114 CAERS reports related to Jif peanut butter.

Operational Period #3: As of 6/17/2022, there are 20 cases from 15 states: AR, AZ, GA (2), IL, IN, MA, MO (2), MI, NC (2), NY, OH, SC, TX (2), VA, WA, WV. Isolation dates range from 2/20/2022 to 5/24/2022. On 6/1/2022, ORA HAF 5E (CIN) relayed results of sampling conducted by OH Department of Agriculture; eight samples of Jif peanut butter unrelated to any cases were negative for *Salmonella*, *E. coli*, and *Listeria monocytogenes*. On 6/3/2022, HAF 1E (NYK) relayed that both jars of leftover Jif peanut butter (lot code of 20174250205:34 and 2033006111256) collected from a NY case for were negative for *Salmonella*. On 6/7/2022, CFSAN received notice that J.M. Smucker intends to (b)(4) _____, which has not been implicated in the outbreak. On 6/8/2022, ORA HAF 5E (CIN) held a call with J.M. Smucker to notify them firm that the (b)(5) _____

On 6/9/2022, ORA HAF 5E (CIN) issued an FDA Form 483 to J. M. Smucker (Lexington, KY) with two observations: 1) Hazard analysis did not identify a hazard that required a preventive control and 2) Equipment and utensils were not designed and constructed to be adequately cleaned or maintained to protect against contamination. On 6/15/2022, ORA HAF 5E (CIN) provided an update from J.M. Smucker, the Lexington, KY facility began producing in a portion of the facility, but product is placed on hold during the re-validation process. As of 6/16/2022, CFSAN/OAO has provided a summary of 1412 CAERS reports related to Jif peanut butter and OEO reports that 326 consumer complaints have been submitted to FDA regarding Jif peanut butter.

5. Site Safety Plan Required? Yes No
Approved Site Safety Plan(s) Located at:

6. Incident Action Plan (the items checked below are included in this Incident Action Plan):

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<input type="checkbox"/> ICS 203 <input type="checkbox"/> Map/Chart <input type="checkbox"/> ICS 204 <input type="checkbox"/> Weather Forecast/Tides/Currents <input type="checkbox"/> ICS 205 <input type="checkbox"/> ICS 206 <input type="checkbox"/> ICS 208	Other Attachments: <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____
7. Prepared by: Name: Sharon Seelman Position/Title: <u>Planning Chief</u> Signature: <u>Sharon Seelman</u>	
8. Approved by Incident Commander: Name: Brooke Whitney Signature: <u>Brooke Whitney</u>	
ICS 202	IAP Page _____ Date/Time 06/17/2022 @ 2pm ET

Updated by FDA 2/2011

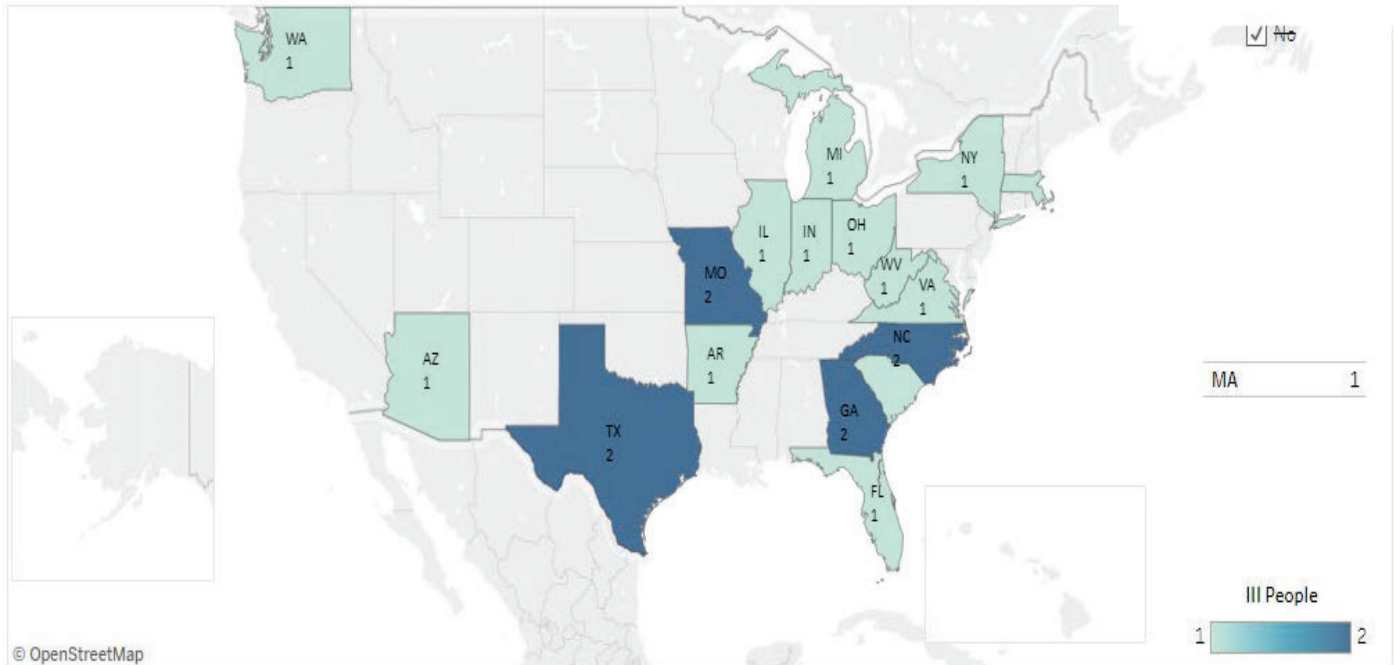
INCIDENT BRIEFING (ICS 201), Adapted for FDA

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4. Map/Sketch

Date: 7/13/2022

Salmonella Senftenberg/Peanut Butter/May 2022



https://www.ncbi.nlm.nih.gov/pathogens/tree#Salmonella/PDG000000002.2442/PDS000031814.109?key=q-UzfUUfgGvXq7cHtsvrfBoXc5Kfc8YK_nSOHe9QtBr2VbgV2FU

5. Situation Summary and Health and Safety Briefing

Salmonella Senftenberg (2205MLJMP-1)/Peanut Butter (suspect)/May 2022

On 4/25/2022, the CFSAN OAO Bioinformatics Team notified CORE Signals about a potential retrospective outbreak involving five clinical isolates, surrounded by a large number of peanut butter and environmental isolates. The peanut butter and environmental isolates were collected by (b)(4) (b)(4); under contract to a private company) between 2014 and 2018. The (b)(4) samples can be identified by the acronym "(b)(4)" in NCBI and are noted as coming from KY. The specific identity of the manufacturer was not disclosed by (b)(4).

On 4/25/2022, after reviewing the isolates with OAO, CORE Signals reached out to CDC about the possibility of naming and coding the cluster. According to PulseNet, the number of clinical isolates identified over the specified time frame did not meet the criteria for identifying the isolates as a cluster and initiating an epidemiologic investigation.

On 5/9/2022, the group of isolates was identified as a PulseNet cluster and was given the cluster code, 2205MLJMP-1; at that time there were 8 clinical isolates uploaded to PulseNet within the past 60 days.

As of 5/19/22, this sample-initiated retrospective cluster consists of 10 cases from 8 states: GA (2), IL, MO, NC, OH, TX (2), VA, and WA. Cases are highly related by 0-5 SNPs (avg 1) and by 0-2 alleles by cgMLST. Isolation dates range from 2/20/22 to 4/24/22, with 6/10 cases occurring in April 2022. Cases range in age from 0 – 83 years, with a median age of 49. 70% (7/10) of cases are female. There has been one hospitalization and no reported deaths. The lag period for this cluster is 30 days.

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Preliminary exposure information as reported by CDC (as of 5/18/2022) indicates 4/4 cases report peanut butter and 3/4 specifically report JIF brand (variety not specified).

Cases reporting 'Yes' to peanut butter, as well as JIF, include:

- IL2__S220062394: 'Yes' to peanut butter
- OH__2022005733: 'Yes' to peanut butter; 'Yes' to JIF
- GA__22C0040673: 'Yes' to peanut butter; 'Yes' to JIF
- VA__R220407058: 'Yes' to peanut butter; 'Yes' to JIF

Based on the WGS link between the clinical and peanut butter isolates, combined with preliminary epidemiological evidence provided by CDC, peanut butter is considered the suspect vehicle associated with this retrospective outbreak.

On 5/19/2022, CDC will host a multi-state to discuss this cluster and gather additional epidemiologic information. During the call, it is anticipated that CDC will discuss the need for a peanut butter specific focused questionnaire, collection of lot code information, as well as consumer product, and possibly retail sampling. CORE Signals has passed along a request to CDC to gather all lot code information from cases.

'J.M. Smucker' Firm Information

JIF is a brand of peanut butter that is manufactured by 'JM Smucker, LLC', and is manufactured in several facilities across the US. In 2017, JIF was named the leading peanut butter brand in the US and was noted to control over 30% of the market share, triple that of Skippy brand peanut butter (noted as the second leading brand in the US). This market share translates into sales over \$587 million US dollars in 2017 compared to \$195 million dollars for Skippy .

'J.M. Smucker' Lexington, KY Firm Information

'J.M. Smucker LLC', is located in Lexington, KY (FEI: 1021607; 767 Winchester Rd Lexington, KY 40505), and is (b)(4), (b)(4).

The 'J.M. Smucker', Lexington, KY facility manufactures JIF brand products exclusively, and is the (b)(4). JIF brand products manufactured from this facility can be identified by the lot code (b)(4).

The Lexington, KY facility was last inspected by KY state partners in December 2021 as a full scope PC inspection and was classified 'NAI'.

Per the inspection report, this firm is (b)(4)% wholesale with (b)(4)% interstate commerce. It was noted this facility maintains (b)(4) lines for peanut butter production in a variety of spreads and sizes, including: snack size to go cups, 12 oz., 13 oz., 16 oz., 28 oz., 40oz., and 48 oz. containers. Products are labeled with a (b)(4)-year shelf life for jars and (b)(4) months for small cups.

No environmental swabbing was conducted during this inspection.

According to the inspection report, the firm maintains a sanitation, as well as environmental monitoring program. The environmental monitoring program conducts (b)(4), located at (b)(4) sampling sites throughout the facility, with at least (b)(4) swab tests (b)(4), (b)(4), including (b)(4) test.

Since 2010, the Lexington, KY facility has been inspected four times by FDA: 2010, 2011, 2015 and 2018. During the 2010 inspection, environmental swabbing was conducted, and a positive Salmonella Senftenberg sample was identified. The isolate was analyzed and maintained by DEN Lab. The CFSAN OAO Bioinformatics Team has analyzed the isolate and provided the following interpretation: Salmonella enterica sample number 549178 (Smucker, Lexington KY, 201) subsample was analyzed and is considered a match to a large number of peanut butter and environmental isolates that were submitted to NCBI from 2014 to 2018. The isolates are related by 0-24 SNPs (mean 7.33 SNPs). It is also related to the current clinical cluster of isolates (2205MLJMP-1) by 14-17 SNPs (mean 15.2 SNPs). Since there is a span of approximately 12 years between the collection of sample #549178 and the clinical isolates and there is an expected amount of genetic drift over time, OAO's genetic interpretation suggests that sample 549178 matches the clinical isolates in illness cluster 2205MLJMP-1. Additionally, the predicted serotype for sample 549178 is Salmonella Senftenberg.

In 2011, FDA reinspected the Lexington, KY 'J.M. Smucker' facility in follow-up to the 2010 positive Salmonella isolate. During the inspection, environmental swabs were collected, and all swabs tested negative for Salmonella. This

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inspection was classified 'NAI'.

In 2015, FDA conducted a comprehensive inspection at the Lexington, KY facility, for which several 'closed' consumer complaints were evaluated. Complaints were dated from 2014 and 2015 and included mention of foreign objects and illness (CC #s: 138523,138587, 138790,138892, and 136607). During the inspection, no samples were collected. This inspection was classified 'VAI' and a 483 was issued.

In 2018, FDA preformed a GMP/ limited scope PC inspection at the Lexington, KY facility. During the inspection, the environmental monitoring program was outlined, which included mention of sending samples to (b)(4) for analysis. The report notes, " (b)(4)

All samples are sent to (b) (4) and are analyzed for Listeria monocytogenes, E. coli and Salmonella." According to the firm, " (b)(4)

During the inspection, it was noted the firm's most recent positive sample was identified on 10/11/2017 ((b)(4) with corrective actions concluding on 10/16/2017. The firm declined to provide additional information on the positive sample. No samples were collected during this inspection, and the inspection was classified NAI.

Since 2020, three consumer complaints have been received for the Lexington, KY 'J. M. Smucker' facility. Two complaints reference illness (172592 and 172947), and one complaint references a foreign substance (170149).

FDA and the state of KY (under state contract) have inspected the 'J.M. Smucker' Lexington, KY facility several times following the identification of the 2010 positive Salmonella sample. However, it should be noted that swabbing at this facility has not been conducted since 2011. According to the EIRs for both the FDA and State inspections, environmental monitoring records were requested by the investigators, but the firm denied the requests.

Other JIF brand peanut butter manufacturing sites include (b)(4) plants in (b)(4). The plants located in (b)(4) are reported to produce (b)(4). From EIR reports obtained for these plants, it is noted that these plants receive JIF brand peanut butter from either the (b)(4).

'J.M. Smucker'/JIF Peanut Butter Manufacturing Sites in (b)(4)

- 'J.M. Smucker Co'; (b)(4); FEI: (b)(4)
- o The firm is located (b)(4), and was last inspected on 12/16/2019.
- o Per the 2019 inspection report, the (b)(4) campus consists of (b)(4) – the (b)(4). The (b)(4) (b)(4)
- o The firm (b)(4) (b)(4)
- o The report notes that environmental testing is conducted (b)(4) for (b)(4), and that samples are sent to (b)(4) for testing.
- o During the 2019 inspection, no violations were cited, and the inspection was classified as 'NAI'.
- o This firm has received one consumer complaint in February 2021 (166848,). The complaint was in reference to a peanut butter product and was noted as containing, "...a greenish, purple and reddish," substance. This complaint was not affiliated with an illness report.

- 'J.M. Smucker, (b)(4); FEI: (b)(4)
- o This facility is located at (b)(4), (b)(4), and was last inspected on 02/24/2021.
- o Per the 2021 inspection report, the (b)(4) campus consists of (b)(4) plants – (b)(4). The (b)(4)

Retail package sizes include 15.5 oz., 16 oz., 27.3 oz., 28.0 oz., and 40 oz. plastic jars; (b)(4) (b)(4) peanut butter is sent to (b)(4). The firm (b)(4)

The report notes that environmental testing is done (b)(4) on (b)(4) for Listeria, Salmonella, and E. coli; and that analysis is conducted by (b)(4). During the 2021 inspection, environmental test results for 12/2020, 1/2021,

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<p>2/3/2021 and 2/22/2021 were reviewed, and no issues were identified.</p> <ul style="list-style-type: none"> o During the 2021 inspection, no objectionable conditions were cited, and the inspection was classified NAI. <p>'JM Smucker' (b)(4)</p> <ul style="list-style-type: none"> • J.M. Smucker (b)(4); FEI: (b)(4) o This facility is located at (b)(4) and was last inspected on 02/12/2019. • J.M. Smucker (b)(4); FEI: (b)(4) o This facility is located at (b)(4), and has never been inspected. The firm registration date is listed as (b)(4). <p>Other Firms of Possible Interest</p> <ul style="list-style-type: none"> • J.M. Smucker plant; FEI: (b)(4) o This facility is located at (b)(4), and manufactures '(b)(4)' brand peanut butter. This facility was last inspected on 9/30/2021. o It should be noted that JIF brand peanut butter was not mentioned in the report as one of the Smucker's brands of peanut butter manufactured at this facility. o Products manufactured from this facility can be identified by the lot code '(b)(4)'. • (b)(4); FEI: (b)(4) o This facility is located at (b)(4), and manufactures (b)(4). The facility was last inspected on 8/25/2021. o Products manufactured from this facility can be identified by the lot code '(b)(4)'. <p>This incident is being transferred to CORE Response Team 1 based on the following rationale:</p> <ul style="list-style-type: none"> • This is a retrospective illness cluster of Salmonella Senftenberg, which is considered to be ongoing with the most recent case occurring in late April 2022. • Based on WGS data, inspectional history, and preliminary epidemiologic information obtained by CDC, CORE Signals (in collaboration with CDC) has identified JIF brand peanut butter manufactured at the Lexington, KY 'JM Smucker' facility as the suspect vehicle for this incident. • Response coordination is needed for follow-up at the manufacturing facility and to coordinate any product and regulatory actions that may need to occur. • This is a repeat pathogen/commodity pair of significant interest to the FDA foods program. <p>This is a retrospective illness cluster of Salmonella Senftenberg, which is considered to be ongoing with the most recent case occurring in late April 2022. Based on WGS data, inspectional history, and preliminary epidemiologic information obtained by CDC, CORE Signals (in collaboration with CDC) has identified JIF brand peanut butter manufactured at the Lexington, KY 'JM Smucker' facility as the suspect vehicle for this incident. Response coordination is needed for follow-up at the manufacturing facility and to coordinate any product and regulatory actions that may need to occur. This is a repeat pathogen/commodity pair of significant interest to the FDA foods program.</p>		
6. Prepared by: Name: Ashley Grant		Position/Title: Signals Team Member Signature:
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7. Current and Planned Objectives:

(b) (5)

8. Current and Planned Actions, Strategies, and Tactics:

Time:	Actions:
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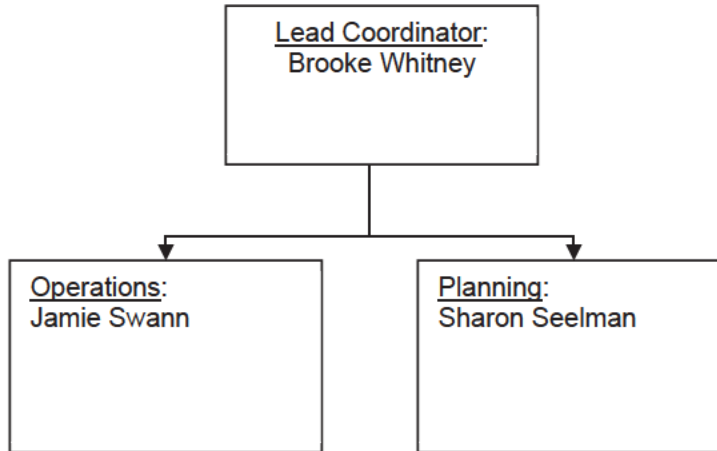
6. Prepared by: Name: Ashley Grant	Position/Title: Signals Team Member	Signature:
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9. Current Organization (fill in additional organization as appropriate):



6. Prepared by: Name: Ashley Grant

Position/Title: Signals Team Member

Signature:

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10. Resource Summary:					
Resource	Resource Identifier	Date/Time Ordered	ETA	Arrived	Notes (location/assignment/status)
Kim Langelo	Office of Human and Animal Foods Operations - East (OHAFO-E)				
Nicole Vaught	Office of Human and Animal Foods Operations - East (OHAFO-E)				
William Muszynski	Office of Human and Animal Foods Operations - East (OHAFO-E)				
Nelson Venario	Office of Human and Animal Foods Operations - East (OHAFO-E)				
Marianela Aponte Cruz	Office of Human and Animal Foods Operations - East (OHAFO-E)				
LT Sana Elassar	Office of Human and Animal Foods Operation				

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	s - West (OHAFO-W)					
Erin Dugan	Office of Human and Animal Foods Operations - West (OHAFO-W)					
Holly Miller	Office of Human and Animal Foods Operations - West (OHAFO-W)					
Hermie Franscisco	Office of Human and Animal Foods Operations - West (OHAFO-W)					
Nicole Yuen	Office of Human and Animal Foods Operations - West (OHAFO-W)					
Linda Stewart	Office of Human and Animal Foods Operations (OHAFO)					
Nicole Clausen	Office of Human and Animal Foods Operations (OHAFO)					

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10. Resource Summary:

Monali Yajnik	Office of Human and Animal Foods Operations (OHAFO)				
Darcy Brillhart	Office of Regulatory Science				
Jennifer Kinney	Office of Regulatory Science				
ORA OSPOP ENFORCEMENT Recall Operations Branch	Office of Partnerships and Operations Policy (OPOP)				
Catherine Beer	Office of Partnerships and Operations Policy (OPOP)				
Kate Nagy	Office of Human and Animal Foods Operations (OHAFO)				DoD Liaison
Ginny Keys	Office of Criminal Investigations (OCI)				
Heath Mott	Office of Criminal Investigations (OCI)				
Claudia Ahiabor	Office of the Chief Counsel				
Jason Cornell	Office of Global Policy and Strategy				
Dana Kappel	Office of Global Policy and Strategy				
Capt Nicole Conklin	Office of Global Policy and Strategy				

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10. Resource Summary:						
Sheila VanTwyer	Office of Operations				Office of Emergency Operations - NCCC	
Jeff Read	International Affairs Staff					
Oliver Ou	Office of Analytics and Outreach				CAERS staff	
Nichole Nolan	Office of Analytics and Outreach				CAERS staff	
Stephanie Kenez	Office of Analytics and Outreach				CAERS staff	
Ben Warren	Office of Food Safety					
Patricia Homola	Office of Food Safety					
David Rotstein					CVM	
Ashley Grant	Coordinated Outbreak Response and Evaluation Network (CORE)					
Alvin Crosby	Coordinated Outbreak Response and Evaluation Network (CORE)				Team Lead	
Brooke Whitney	Coordinated Outbreak Response and Evaluation Network (CORE)				Incident Lead	
Sharon Seelman	Coordinated Outbreak Response and Evaluation				Planning Chief	

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10. Resource Summary:					
	Network (CORE)				
Johnson Nsubuga	Coordinated Outbreak Response and Evaluation Network (CORE)				Operations Chief
Jamie Swann	Coordinated Outbreak Response and Evaluation Network (CORE)				Operations Chief
Brenda Zimmer	Office of Human and Animal Foods Operations - East (OHAFO-E)				
Wilbur Huggins	Office of Human and Animal Foods Operations - East (OHAFO-E)				
Lindsay Bertling	Office of Human and Animal Foods Operations - East (OHAFO-E)				
Joseph Cooper	Office of Human and Animal Foods Operations - East (OHAFO-E)				
Valeria Moore	Office of Human				

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	and Animal Foods Operation s - East (OHAFO- E)				
Meredith Sheridan	Office of Human and Animal Foods Operation s - East (OHAFO- E)				
Scott Jepson	Office of Human and Animal Foods Operation s - West (OHAFO- W)				filling in for Erin through July 9, 2022
Kelsey Volkman	Office of Human and Animal Foods Operation s - West (OHAFO- W)				
Travis Hunt	Office of Human and Animal Foods Operation s - West (OHAFO- W)				
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1. Incident Name: <u>Salmonella Senftenberg/Peanut Butter/May 2022</u>		2. CORE Incident Number: 1067		3. Date/Time Initiated: Date: 7/13/2022 Time: 4:32 PM	
10. Resource Summary:					
Alexandra Palacios	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
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	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				CDC Comms
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ICS 201, Page 4		Date/Time: 7/13/2022 4:32 PM EDT			



Salmonella Senftenberg/Peanut Butter/May 2022

CARA #1067

Incident Summary Report

July 15, 2022

Authors:

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ABSTRACT

On 4/25/2022, the CFSAN Office of Analytics and Outreach (OAO) Bioinformatics Team notified CORE Signals of a retrospective cluster involving five clinical isolates of *Salmonella* Senftenberg and a number of peanut butter and environmental isolates. On 5/9/2022, PulseNet coded eight isolates as a new cluster (2205MLJMP-1). Subsequent epidemiologic evidence collected from cases supported peanut butter as the vehicle. Additionally, whole genome sequencing analysis was conducted on an isolate from 2010 collected at J.M. Smucker in Lexington, KY and found to be related to the outbreak strain. Lot codes of Jif peanut butter collected from confirmed cases supported exposure to peanut butter manufactured in Lexington, KY. FDA/ORA Human and Animal Foods Division 5 East (HAF 5E), in collaboration with state partners from KY, conducted an inspection with environmental sampling at J.M. Smucker in Lexington, KY. Environmental swabs were collected at J.M. Smucker and five states collected various product samples of Jif peanut butter. No *Salmonella* was recovered in any samples collected during this outbreak investigation. On 5/20/2022, J.M. Smucker Company issued a voluntary recall for products manufactured at the Lexington, KY facility manufactured (b)(4). Both FDA and CDC published webposts regarding the outbreak. Based on the epidemiologic information, identification of a single manufacturing facility that could be responsible, and historic laboratory evidence, the vehicle for this outbreak is confirmed as Jif peanut butter. This outbreak included a total of 21 cases from 17 states: AR (1), AZ (1), FL (1), GA (2), IL (1), IN (1), MA (1), MO (2), MI (1), NC (2), NY (1), OH (1), SC (1), TX (2), VA (1), WA (1), and WV (1).

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SIGNALS AND SURVEILLANCE ACTIVITIES

On 4/25/2022, the CFSAN Office of Analytics and Outreach (OAO) Bioinformatics Team notified CORE Signals of a retrospective cluster involving five clinical isolates and a number of peanut butter and environmental isolates. The peanut butter and environmental isolates surrounding the clinical isolates were submitted by (b)(4) and obtained under contract to a private company between 2014 and 2017. The minimum metadata provided with the (b)(4) isolates identified KY as the site of origin. At the time, the specific identity of the manufacturer was not disclosed by (b)(4).

On 4/25/2022, after reviewing the cluster with OAO, CORE Signals reached out to CDC about the possibility of coding a cluster for an epidemiologic investigation. At the time, according to PulseNet, the number of clinical isolates identified over the specified time frame did not meet their threshold for identifying the isolates as a cluster and initiating an epidemiologic investigation. However, over the next two weeks, additional clinical isolates were uploaded to NCBI, and on 5/9/2022, PulseNet did code these isolates as a new cluster (2205MLJMP-1). At the time the cluster was named, there were 8 clinical isolates uploaded to PulseNet within the past 60 days.

At the time of transfer, on 5/19/2022, this sample-initiated retrospective cluster consisted of 10 cases from 8 states: GA (2), IL, MO, NC, OH, TX (2), VA, and WA. Cases were highly related by 0-5 SNPs (avg 1) and 0-2 alleles by cgMLST. Isolation dates ranged from 2/20/2022 to 4/24/2022, with 6/10 cases occurring in April 2022. Cases ranged in age from 0 to 83 years, with a median age of 49. 70% (7/10) of cases were female. At the time of transfer, there had been one hospitalization and no reported deaths. The lag period for this cluster was reported as 30 days.

Because the (b)(4) peanut butter and environmental samples were reported as being from KY, CORE Signals reviewed open-source media and FDA firm information, and determined that J.M. Smucker manufactures JIF brand peanut butter at a facility in Lexington, KY. Upon review of this firm's inspectional history, CORE Signals noted that during an FDA inspection in 2010, environmental swabbing at this facility yielded *Salmonella* Senftenberg. CORE Signals requested a comparison of this historical isolate to the current clinical clusters. The isolate was subsequently analyzed by OAO and reported to be a match to the peanut butter and environmental (b)(4) isolates identified in NCBI from 2014 to 2017, and to the clinical isolates included in the current cluster. Specifically, the 2010 sample was noted to be related to the (b)(4) isolates by 0-24 SNPs (mean 7.33 SNPs), and to the 2022 cluster of clinical isolates (2205MLJMP-1) by 14-17 SNPs (mean 15.2 SNPs). Based on the intervening time period of 12 years between the collection of the 2010 sample (#549178) and the clinical isolates, and with an average assumption of genetic evolution over time of 1-2 snps, OAO concluded that sample 549178 matched the clinical isolates in illness cluster 2205MLJMP-1.

FDA and the state of KY (under state contract) inspected the 'J.M. Smucker' Lexington, KY facility several times following the identification of the 2010 positive *Salmonella* sample. Swabbing and samples had not been collected by regulatory authorities since 2011 and all subsequent inspections were classified 'NAI'. 'J.M. Smucker', Lexington, KY facility (FEI: 1021607) is the primary manufacturer of JIF brand peanut butter and this location was identified by the lot code "425".

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CORE Signals summarized the firm research and related FDA sample for CDC, suggested that the epidemiologic investigation include questions about peanut butter, and identified JIF brand peanut butter as an item of particular interest. Preliminary exposure information reported by CDC on 5/18/2022 indicated 4/4 cases reported peanut butter and 3/4 specifically reported JIF brand (variety not specified).

Based on the WGS link between the clinical and peanut butter isolates, combined with preliminary epidemiological evidence provided by CDC, peanut butter was considered the suspect vehicle associated with this retrospective outbreak. As this determination was made and based on the whole genome sequencing evidence linking FDA's 2010 sample to the current outbreak, ORA initiated an inspection at J.M. Smucker on 5/19/2022.

This incident was transferred to CORE Response Team 1 based on the following rationale:

- This was a retrospective illness cluster of *Salmonella* Senftenberg, which at the time, was considered ongoing.
- Based on WGS data, inspectional history, and preliminary epidemiologic information obtained by CDC, CORE Signals (in collaboration with CDC) identified JIF brand peanut butter manufactured at the Lexington, KY 'JM Smucker' facility as the suspect vehicle for this incident.
- Response coordination was needed for follow-up at the manufacturing facility and to coordinate product and regulatory actions.
- *Salmonella* and peanut butter are a repeat pathogen/commodity pair and are of significant interest to the FDA foods program.

EPIDEMIOLOGY

In total, this outbreak included 21 cases from 17 states (AR (1), AZ (1), FL (1), GA (2), IL (1), IN (1), MA (1), MI (1), MO (2), NC (2), NY (1), OH (1), SC (1), TX (2), VA (1), WA (1), and WV (1)). Isolation dates range from 2/20/2022 to 5/24/2022 while reported onset dates range from 2/19/2022 to 5/23/2022. Ages ranged from <1 to 85 years (median: 59 years), and 75 % of cases were female. Of 13 patients with outcome information, four were hospitalized; there were no reported deaths. All clinical isolates were related at 0–2 alleles by cgMLST with common allele code SALM1.0 - 6738.1.5.21.2. A case was defined as infection with *Salmonella* Senftenberg whose isolate was closely related by whole genome sequencing within 0–2 alleles and an isolation date from 2/20/2022 – 5/24/2022.

Given the proximity in NCBI to several peanut butter isolates, CDC and FDA initially suspected peanut butter as a vehicle of interest. CDC held a state call and deployed a peanut butter supplemental questionnaire on 5/20/2022. Of 13 patients with information, all reported Jif brand peanut butter (100%).

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CDC closed this investigation on 6/28/2022 as an outbreak with a confirmed vehicle of peanut butter. This investigation will be reported to NORS with ID 2205MLJMP-1. CDC provided a summary of the outbreak to state partners on 7/14/2022.

LABORATORY

FDA collected an environmental sample consisting of 206 environmental swabs, and state partners collected at least 14 product samples for *Salmonella* testing. *Salmonella* was not isolated from any of the state or FDA samples.

FDA Samples

On 5/20/2022, HAF 5E collected 206 environmental swabs at J.M. Smucker Company in Lexington, KY (Sample #1139991). These were shipped for Saturday Delivery to NFFL for *Salmonella* analysis. On 5/23/2022, ORA/ORS notified CORE that 27 of the 206 subs were negative for *Salmonella*, with the balance pending. On 5/24/2022, ORA/ORS notified CORE that two of the sub samples were Cannot Rule Out (CRO) for *Salmonella*. The two subs that were initially CRO were Sub# 53 = Line 2 Label exit conveyor (Zone 2) and Sub# 195 = 7C Dock (Construction) wheel to compost jack (Zone 3). Ultimately, on 5/31/2022, ORA ORS reported the 206 environmental swabs collected at J.M. Smucker Company in Lexington, KY (Sample #1139991) tested negative for *Salmonella*.

State Samples

Five states collected product samples. CORE requested state sampling of product only in specific scenarios, as outlined by the following guidance provided in Operational Briefing #1 on 5/24/2022:

Sampling guidance for FDA state partners – Complaints

- Determine if the complainant has a recalled product or not.
- If the complaint has a reported case of *Salmonella* with health care provider visit, AND a non-recalled Jif product, please ask them to hold the product.
- If the state has resources, please analyze the sample for *Salmonella*. If resources do not allow, please contact your ERC to consider transfer of the consumer product to FDA for testing. Samples associated with confirmed cases of *Salmonella* serotype Senftenberg will priority.
- We believe these steps will ensure a reasonable number of product samples of greatest interest, but we also recognize that some confirmed *Salmonella* cases may not be related to peanut butter consumption.

Sampling guidance for state partners – Confirmed cases in outbreak

- We know there is interest in sampling product from confirmed cases in the outbreak. CORE is not specifically requesting this be conducted on recalled products.
- However, if a state does move forward with testing products, please keep your ERC aware of the results.
- If a positive is found, FDA is interested in enumerating the sample in a research capacity.

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Ohio

The Ohio Department of Health (ODH) collected a product later included the recall that was consumed by a case. Based on photos provided, the lot code was 20174250202:30 with best if used by date Jan 17 2023. ODH analyzed this product for *Salmonella*. On 5/31/2022, reported the leftover Jif peanut butter from the OH case tested negative for *Salmonella*.

On 6/1/2022, HAF 5E relayed results of sampling conducted by OH Department of Agriculture; eight samples of Jif peanut butter unrelated to any cases were negative for *Salmonella*, *E. coli*, and *Listeria monocytogenes*. Further details of the collected products were not received or sought.

Texas

On 5/24/2022, HAF 3W (DAL) alerted CORE that TX DSHS collected a case-associated sample of Jif with lot number 2024 425 01 13:26 for *Salmonella* analysis.

New York

On 5/25/2022, NY DOH collected two jars leftover from a NY case included in the outbreak for *Salmonella* analysis. The jar consumed prior to symptom onset has a lot code of 20174250205:34 and the additional jar has a lot code of 2033006111256. On 6/3/2022, HAF 1E (NYK) relayed that both jars were negative for *Salmonella*.

North Carolina

On 5/26/2022, NC state partners collected a sample of peanut butter from an outbreak case. Based on previous information provided by CDC, the case had lots 13514250209:23 and 11534250103:56.

Arizona

AZ tested product that was not recalled and it was negative; associated case not in outbreak (different serotype), but we had been following these consumer complaint-related activities

Whole Genome Sequencing

On 5/18/2022, CFSAN OAO created a WGS report that included ten clinical isolates in the outbreak with the following interpretation:

One *Salmonella enterica* sample number 549178 subsample was analyzed (blue). It matches a large number of peanut butter and environmental isolates that were submitted to NCBI (mean 7.33 SNPs). It is also mean 15.2 SNPs from the clinical isolates in illness cluster 2205MLJMP-1 (red). Since there is a span of approximately 12 years between the collection of 549178 and the clinical isolates, the results show that 549178 matches the clinical isolates in illness cluster 2205MLJMP-1. Predicted serotype: Senftenberg.

Any updates to this information can be viewed in NCBI by searching cluster PDS000031814.109. Sample 549178 was an FDA isolate collected on 6/22/2010 from the J.M. Smucker facility in Lexington, KY. The

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additional environmental and peanut butter isolates referenced above were labeled as from KY and were collected in 2014 (111 isolates), 2015 (1 isolate), 2016 (3 isolates) and 2017 (2 isolates). A verbal confirmation was provided to FDA that these isolates also originated from the J.M. Smucker facility in Lexington, KY.

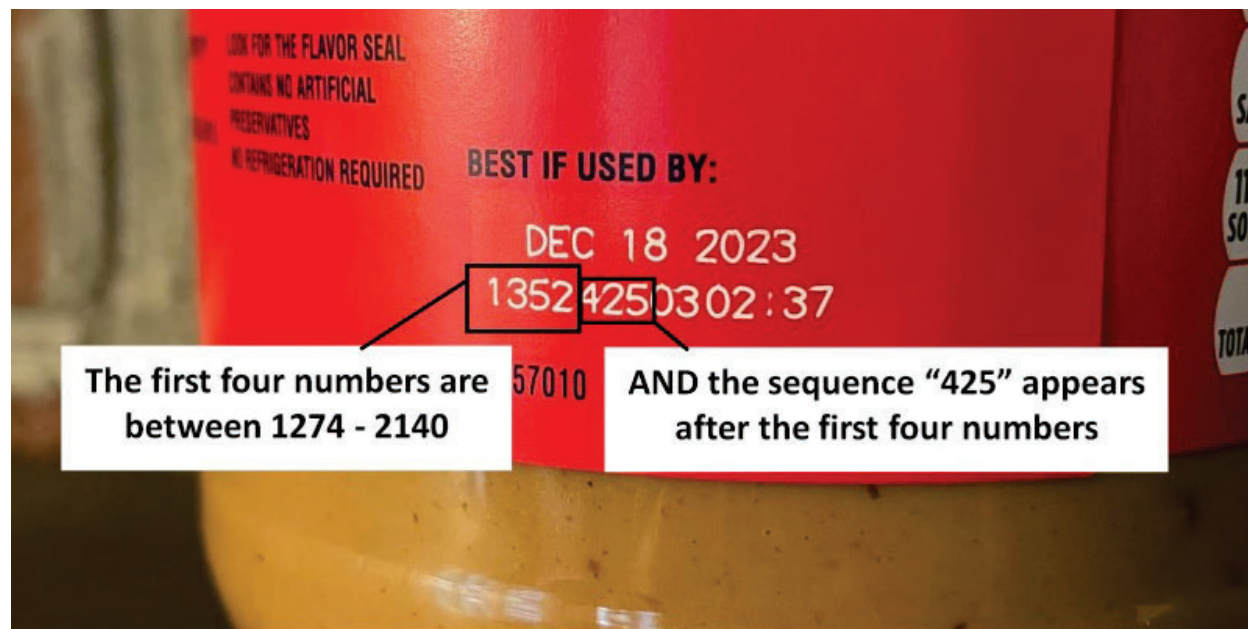
J.M. Smucker reported third party testing had identified *Salmonella* in both environmental and product sampling; however, the firm did not request isolation, speciation, serotyping, or WGS for the positive samples. Combined with the lack of isolation of *Salmonella* from FDA sampling, there is no contemporary non-human WGS information to be incorporated into the overall WGS analysis.

Laboratory Conclusions

While there was historic laboratory evidence that linked this firm to the outbreak strain, no *Salmonella* was identified in environmental sampling conducted at the firm or identified by states through product sampling conducted.

TRACEBACK

A traditional traceback investigation through the distribution chain was not conducted. Rather, traceback initiatives were based on lot code information collected from confirmed cases in the outbreak. An explanation of the lot coding for Jif peanut butter was provided in multiple Establishment Investigation Reports (EIRs) for the J.M. Smucker facility in Lexington, KY. The lot code begins with a (b)(4)



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Where available, lot codes were collected from the cases included in the outbreak investigation who consumed Jif peanut butter. The lot codes provided show manufacturing dates from (b)(4) [REDACTED], with dates clustered in January 2022 (see table below). (b)(4) [REDACTED] manufacturing dates were reported by two cases each: (b)(4) [REDACTED]. Product lot codes were provided by nine confirmed cases. Each case in the outbreak who provided lot code details include at least one product with 425 as digits 5-7; some cases reported exposure to multiple lot codes.

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Case ID	State	Size (oz)	EXP. date	Lot	Peanut Butter Description	Testing / Results?	Recall Status	Purchase location
NC__MB220228-0036-001	NC	16	12/17/2023	13514250209:23	Jif Creamy	no	R	Food Lion
		16	6/2/2023	11534250103:56	Jif Creamy	Yes/negative	N/R	Food Lion
OH__2022005733	OH	40	Not reported	20174250202:30	Low Sodium Jif Natural Creamy	Yes/negative	R	Kroger
AR_AR2209800000124	AR	40	Not reported	2058425091148	Jif Creamy	No	R	Walmart
IL2__S220089781	MO	40	Not reported	20374250200:48	Jif natural creamy	No	R	Hy-Vee
TX__TXACB2200840	TX	16	1/24/2024	2024 425 0113:26	Jif Creamy	Yes/negative	R	HEB
NY__IDR2200019080-01-00	NY	40	1/17/2023	20174250205:34	Jif Natural Creamy	Yes/negative	R	Not reported
		40	2/2/2023	2033006111256	Jif Natural Creamy	Yes/negative	N/R	Not Reported
WA__WA0786368	WA	28	Not reported	1349425, (only first 7 digits provided)	Jif Crunchy Peanut Butter	No	R	Safeway
			Not reported	2008425 (only first 7 digits provided)	Jif Crunchy Peanut Butter	No	R	Safeway
AZ__AZ00161524	AZ		Not reported	2026425 (only first 7 digits provided)	Jif Creamy	No	R	Target
WV__E22M015780	WV		Not reported	20264250304	Not Reported	No	R	Not Reported
VA_R220407058	VA	16	Not Reported	Not Reported	Jif Reduced Fat Creamy	No	n/a	Kroger
IL2__S220062394	IL	40	Not Reported	Not Reported	Jif Creamy Peanut Butter	no	n/a	Kroger

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CFSAN Biostatistics and Bioinformatics Staff WGS Analysis Report

Report Title: Report_220518_Se2205MLJMP-1_220518

Firm Name:

Pathogen: Salmonella

Sample or Facts IDs:

549178

Date Generated: 18 May, 2022

Bioinformatician: Arthur Pightling

WGS Interpretation:

One *Salmonella enterica* sample number 549178 subsample was analyzed (blue). It matches a large number of peanut butter and environmental isolates that were submitted to NCBI (mean 7.33 SNPs). It is also mean 15.2 SNPs from the clinical isolates in illness cluster 2205MLJMP-1 (red). Since there is a span of approximately 12 years between the collection of 549178 and the clinical isolates, the results show that 549178 matches the clinical isolates in illness cluster 2205MLJMP-1. Predicted serotype: Senftenberg.

NCBI SNP Cluster ID(s): PDS000031814.109

Cluster(s) can be monitored by searching for ID here.

CFSAN SNP Pipeline Version: v2.2.1.

See below for phylogenetic clusters (if they were generated).

References

- Information about the CFSAN SNP Pipeline can be found <https://peerj.com/articles/cs-20/>.
 - Information on the interpretation of SNP distances and those clusters can be found <https://www.frontiersin.org/articles/10.3389/fmicb.2018.01482/full>.
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