

## ORIGINAL ARTICLE

# Salmonella Typhimurium Infections Associated with Peanut Products

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## ABSTRACT

**BACKGROUND**

Contaminated food ingredients can affect multiple products, each distributed through various channels and consumed in multiple settings. Beginning in November 2008, we investigated a nationwide outbreak of salmonella infections.

**METHODS**

A case was defined as laboratory-confirmed infection with the outbreak strain of *Salmonella* Typhimurium occurring between September 1, 2008, and April 20, 2009. We conducted two case-control studies, product "trace-back," and environmental investigations.

**RESULTS**

Among 714 case patients identified in 46 states, 166 (23%) were hospitalized and 9 (1%) died. In study 1, illness was associated with eating any peanut butter (matched odds ratio, 2.5; 95% confidence interval [CI], 1.3 to 5.3), peanut butter-containing products (matched odds ratio, 2.2; 95% CI, 1.1 to 4.7), and frozen chicken products (matched odds ratio, 4.6; 95% CI, 1.7 to 14.7). Investigations of focal clusters and single cases associated with nine institutions identified a single institutional brand of peanut butter (here called brand X) distributed to all facilities. In study 2, illness was associated with eating peanut butter outside the home (matched odds ratio, 3.9; 95% CI, 1.6 to 10.0) and two brands of peanut butter crackers (brand A: matched odds ratio, 17.2; 95% CI, 6.9 to 51.5; brand B: matched odds ratio, 3.6; 95% CI, 1.3 to 9.8). Both cracker brands were made from brand X peanut paste. The outbreak strain was isolated from brand X peanut butter, brand A crackers, and 15 other products. A total of 3918 peanut butter-containing products were recalled between January 10 and April 29, 2009.

**CONCLUSIONS**

Contaminated peanut butter and peanut products caused a nationwide salmonellosis outbreak. Ingredient-driven outbreaks are challenging to detect and may lead to widespread contamination of numerous food products.

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**S**ALMONELLA IS A LEADING BACTERIAL cause of gastroenteritis in the United States.<sup>1</sup> Outbreaks of salmonella infections have increasingly been associated with processed foods.<sup>2-4</sup>

In November 2008, a cluster of 35 *Salmonella enterica* serotype Typhimurium isolates with the same uncommon pulsed-field gel electrophoresis (PFGE) pattern was detected in 16 states by PulseNet, the national molecular subtyping network for foodborne disease surveillance (Fig. 1). In late November, a second cluster of 27 *Salmonella* Typhimurium isolates, in 14 states, with two related PFGE patterns was identified. The two clusters had three closely related PFGE patterns, none of which had been previously identified in PulseNet. Since these clusters had similar geographic and age distributions, the PFGE patterns were grouped to define the outbreak strain (Fig. 1 in the Supplementary Appendix, available with the full text of this article at NEJM.org), and the two ongoing investigations were merged. In this report, we describe this nationwide outbreak investigation, identification of food sources, and implementation of control measures.

## METHODS

### CASE DEFINITION

Clinical salmonella isolates are sent to state public health laboratories for serotyping and PFGE subtyping with the use of restriction enzymes *Xba*I and *Bln*I and standard PulseNet protocols<sup>5,6</sup>; results are submitted to PulseNet. We defined a case patient as a person with laboratory-confirmed infection with the outbreak strain of *Salmonella* Typhimurium infection that occurred from September 1, 2008, through April 20, 2009.

### HYPOTHESIS GENERATION

Local and state public health departments conducted routine case-patient interviews in November and December 2008 to gather demographic information and to record exposure histories. No epidemiologic links among cases or large focal clusters were initially identified. A standard hypothesis-generating interview, including questions about 471 types of possible exposures in the week preceding illness, was administered to case patients identified during late November 2008 to early January 2009 whom we were able to contact and who agreed to participate (Fig. 1). Exposures reported were compared with responses from healthy

persons interviewed in the 2006–2007 FoodNet Population Survey.<sup>7</sup> Based on results from “trace-back” and “trace-forward” investigations, additional hypotheses for suspect food products were explored.<sup>8</sup>

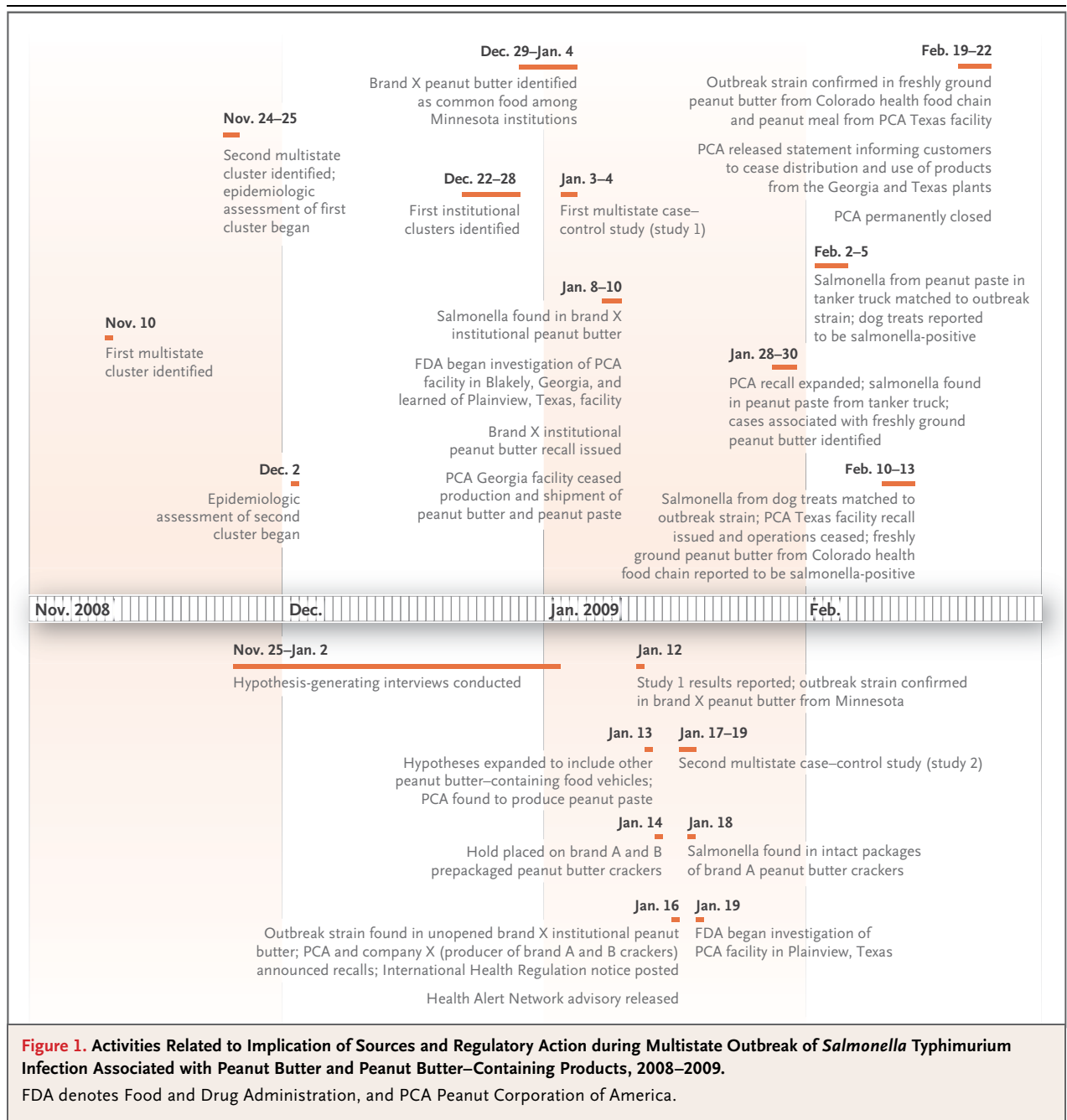
### INSTITUTIONAL INVESTIGATIONS

Clusters of cases in institutional settings were monitored throughout the outbreak. An institutional setting was defined as a hospital, nursing or assisted-living home, long-term care facility, detention center, school, or similar setting. An institutional cluster was defined as two or more cases in an institution. Some health departments, including the Minnesota Department of Health, conducted intensive interviews at institutions, focusing on identification of common foods and trace-back investigations to identify foods served in common among institutions. A case–control study of clusters in institutions was conducted (see the Supplementary Appendix).

### EPIDEMIOLOGIC STUDIES OF CASES NOT LINKED TO INSTITUTIONAL CLUSTERS

Two multistate case–control studies were conducted during January 2009. For both, a case was defined as infection with the outbreak strain (on or after November 1, in study 1, or on or after December 1, in study 2) in a person who did not live in an institutional setting or have household members with diarrhea. Study 1 participants were not eligible for participation in study 2. Controls were persons without diarrhea who were matched to case patients on the basis of age category and neighborhood (see the Supplementary Appendix).<sup>9</sup> Food histories were taken in case patients for the week preceding illness and in controls for the week before the interview (in study 1) and the week before the matched case patient’s onset of diarrhea (in study 2). All study participants provided oral assent.

For the food history, in study 1, participants were asked about eating foods mentioned by a high proportion of respondents in hypothesis-generating interviews, including peanut butter and chicken. In study 2, participants were asked about selected exposures on the basis of significant study 1 results, including peanut butter at home and away from home, roasted peanuts, 13 peanut butter-containing product categories, and 5 frozen chicken products. For both studies, participants were asked about clinical history, institu-



tional and noninstitutional exposures in the week preceding illness, and type, brand, and location of purchase and location of consumption for each exposure.

#### TRACE-BACK INVESTIGATION

State and local health departments and the Food and Drug Administration (FDA) conducted trace-back investigations of implicated food vehicles,

inspected implicated facilities, collected environmental samples, and traced products forward from the implicated facilities through their use as ingredients in other food items.<sup>10–12</sup>

#### LABORATORY INVESTIGATION

Food and environmental samples were collected from the homes of case patients, institutional settings with case patients, and implicated produc-

tion facilities and tested for salmonella by means of standard techniques<sup>13</sup> (see the Supplementary Appendix).

#### STATISTICAL ANALYSIS

Statistical analyses were conducted with the use of SAS software, version 9.2 (SAS Institute). Exposure rates were compared between case patients and controls by means of matched odds ratios with exact 95% confidence intervals. Multivariable analysis was conducted for study 2 with the use of an age-adjusted model (see the Supplementary Appendix).

## RESULTS

#### DESCRIPTION OF THE OUTBREAK

We identified 714 case patients from 46 states (Fig. 2) (also see the Supplementary Appendix). Dates of illness onset ranged from September 6, 2008, to April 4, 2009 (Fig. 3).

#### HYPOTHESIS GENERATION

Among 86 hypothesis-generating interviews received from 26 states, 47 of 81 respondents (58%) reported having been exposed to institutional settings; 56 of 79 (71%) reported eating peanut butter; and 61 of 71 (86%) reported eating chicken. However, respondents reported eating many different types and brands of peanut butter and chicken products.

#### INSTITUTIONAL INVESTIGATIONS

During December 2008, the Minnesota Department of Health identified a cluster of five case patients residing in a long-term care facility (hereafter called facility A) and one case patient in another long-term care facility (hereafter called facility B), both in the same city, as well as two case patients attending one elementary school (Fig. 1). By January 9, 2009, six additional case patients who ate meals in six other institutions were identified. The Minnesota Department of Health and the Minnesota Department of Agriculture reviewed menus and invoices at these nine institutions and identified a common food distributor that distributed the same brand of peanut butter (hereafter called brand X) to all the facilities. Brand X was an institutional peanut butter brand produced by the Peanut Corporation of America (PCA) at their Blakely, Georgia, facility. An open tub of brand X peanut butter from facility A was collected for salmonella testing on January 5.

#### EPIDEMIOLOGIC STUDIES OF CASES NOT LINKED TO INSTITUTIONAL CLUSTERS

##### *Case-Control Study 1*

Study 1 included 65 case patients and 174 matched controls. On univariate analysis, illness was significantly associated with eating peanut butter and peanut butter-containing products (Table 1). Illness was also associated with eating any frozen chicken products but not with any specific product; more than 10% of case patients did not report eating a frozen chicken product. Illness was not associated with eating peanuts or major commercial brands of jarred peanut butter (Table 1).

##### *Ongoing Hypothesis Generation*

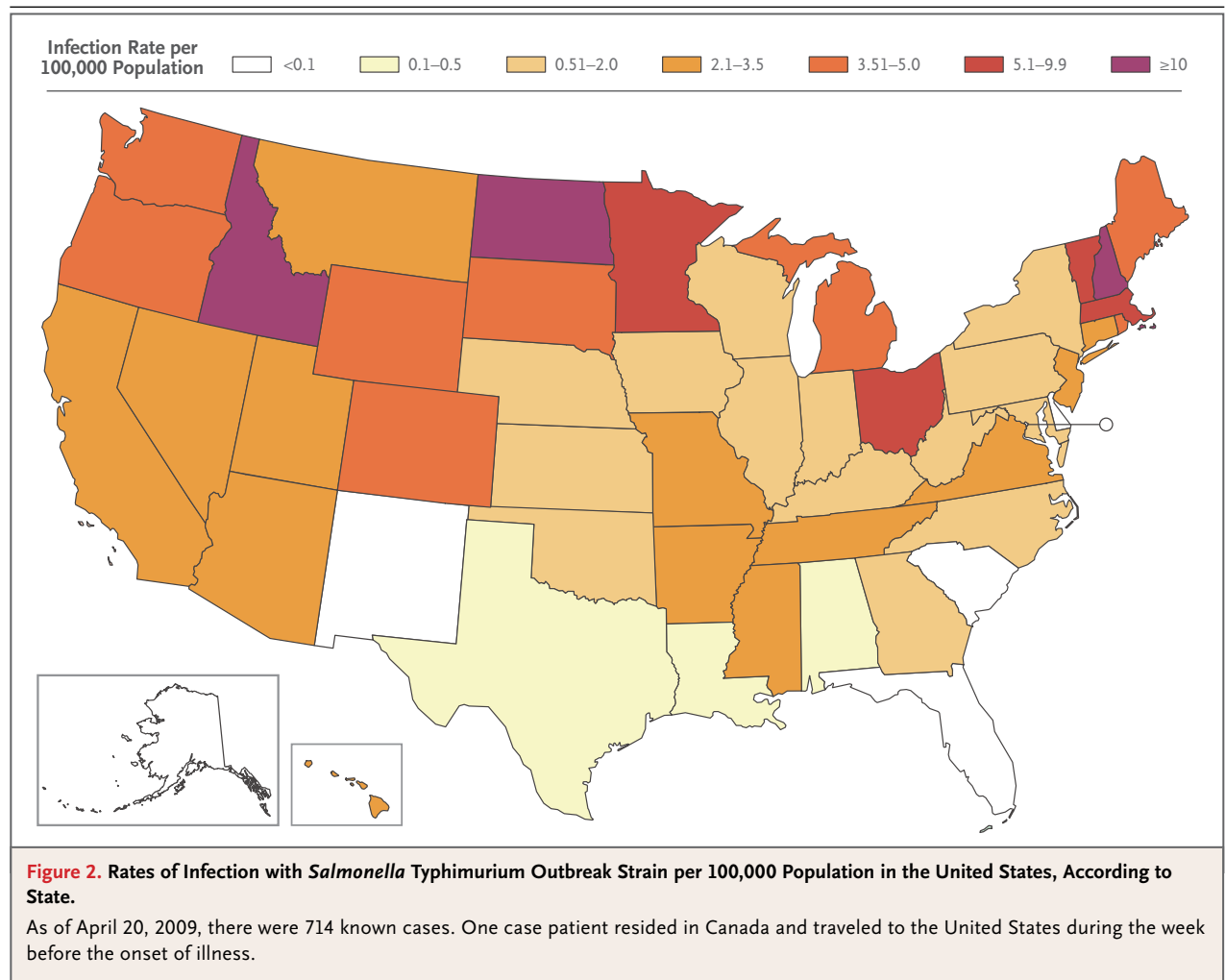
Ongoing interviews indicated that a number of case patients were not residents of institutions or did not report eating peanut butter at institutions. On January 13, 2009, investigators in several states noted that many patients interviewed reported eating other peanut butter-containing products, particularly two brands of prepackaged peanut butter crackers (hereafter called brands A and B). The same day, investigators learned that the Georgia PCA facility also produced peanut paste made from ground roasted peanuts, an ingredient in a variety of widely distributed peanut butter-containing products, including peanut butter crackers. A second case-control study was launched to examine exposures to peanut butter-containing foods.

##### *Case-Control Study 2*

Study 2 included 95 case patients and 362 matched controls. Illness was significantly associated with eating any prepackaged peanut butter crackers as well as specifically brand A or brand B peanut butter crackers (Table 2). Illness was significantly associated with eating peanut butter outside the home and attending a school or other institution but was not associated with consumption of any retail brand of peanut butter, frozen chicken products, or other peanut butter-containing products (Table 2). In an age-adjusted multivariate analysis, three exposures only — eating peanut butter outside the home, eating any peanut butter crackers, and eating brand A or B peanut butter crackers — were associated with illness (Table 2).

#### ADDITIONAL INVESTIGATIONS

From January 30 through February 5, case interviews by epidemiologists at the Colorado Department of Public Health and Environment identi-



fied seven case patients who consumed in-store ground peanut butter at different locations of a health food store chain (hereafter called chain A).

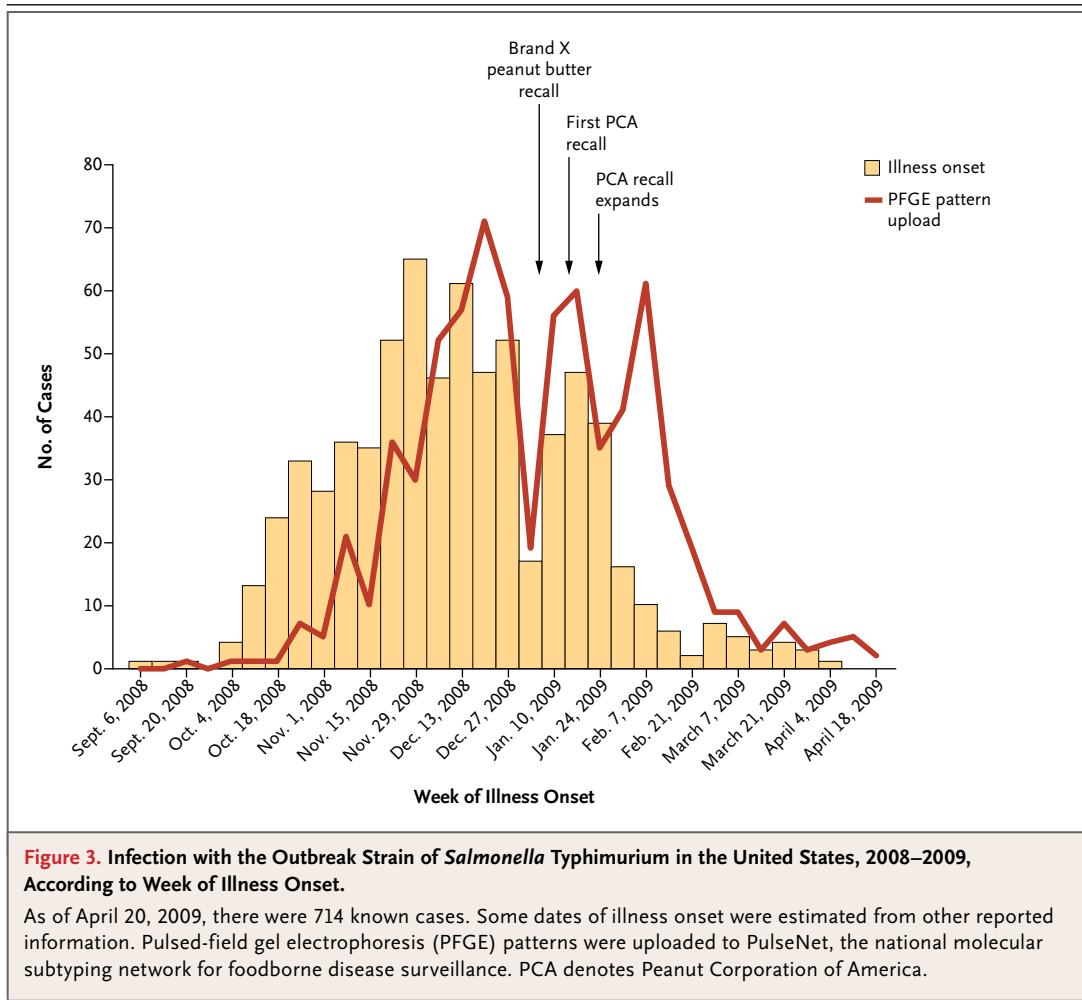
#### TRACE-BACK INVESTIGATION

Product trace-backs from institutions revealed that brand X peanut butter produced at the PCA facility in Blakely, Georgia, was distributed in bulk only to institutions and food service companies. A joint FDA and Georgia Department of Agriculture investigation at the Georgia PCA facility found multiple possibilities for salmonella contamination, including evidence of rain and other water leakage into storage areas used for roasted peanuts, practices that allowed for cross-contamination between raw and roasted peanuts, and uncertainty as to whether the peanut roaster routinely reached a temperature sufficient to kill salmonella.<sup>12</sup>

*Salmonella* Typhimurium had been isolated from peanut paste at the Georgia PCA facility during

routine product testing in September 2008. The study laboratory retested a sample of the peanut paste but was unable to isolate *Salmonella* Typhimurium again. This peanut-paste lot was shipped from the Georgia PCA facility to other states. The lots of roasted peanuts used to make this peanut paste were also used to make multiple lots of peanut butter. During routine product testing at the Georgia PCA facility from July 2007 through January 2008, salmonella of several serotypes had been isolated from a variety of peanut products; all positive products were retested, found to be negative for salmonella, and distributed.<sup>12</sup>

Trace-back from Colorado chain A revealed that roasted peanuts for in-store ground peanut butter were purchased exclusively from a second PCA facility in Plainview, Texas (Fig. 1). This facility principally roasted peanuts for distribution and produced peanut meal used to make peanut butter and peanut paste.<sup>11</sup> No peanut butter was pro-



duced at this facility. Peanuts and peanut meal were transferred between the Georgia and Texas facilities, and products from the Texas plant were used to make peanut butter and paste at the Georgia facility. An inspection at the Texas PCA facility identified several sanitation problems that could have led to salmonella contamination, including rodent-accessible entryways, an unsealed air-handling system, and rain leakage into peanut storage areas.<sup>10</sup>

#### LABORATORY INVESTIGATION

On January 12, 2009, the Minnesota Department of Agriculture laboratory isolated the outbreak strain in the open tub of brand X peanut butter from facility A. The outbreak strain was subsequently isolated from an unopened container of brand X peanut butter in Connecticut and an unopened package of brand A peanut butter sand-

wich crackers in Canada that were purchased in the United States (see the Supplementary Appendix). Approximately 315 food and environmental samples from 24 states and Canada were cultured for salmonella; the outbreak strain was isolated from 17 food samples (Fig. 1). All PFGE patterns defined as the outbreak strain were identified in one or more food items produced between August 21 and December 6, 2008. The outbreak strain was not isolated from environmental samples collected in the Georgia or Texas PCA facilities; however, other salmonella strains were isolated there (see the Supplementary Appendix).

#### CONTROL MEASURES

Throughout the outbreak, multiple public advisories were issued, recommending that consumers avoid eating implicated peanut butter products.<sup>14,15</sup> On January 9, 2009, the PCA ceased production



**Table 1. Odds Ratios of *Salmonella* Typhimurium Infection in Case Patients vs. Controls in 12 States in Study 1, January 3–4, 2009, According to Ingested Food Item.\***

Food Item	Case Patients (N = 65)	Controls (N = 174)	Odds Ratio (95% CI)	P Value
	no./total no. (%)			
Previously frozen chicken products	18/52 (35)	23/161 (14)	4.6 (1.7–14.7)	0.002
Any peanut butter	43/63 (68)	80/168 (48)	2.5 (1.3–5.3)	0.007
Any peanut butter–containing product	47/62 (76)	104/168 (62)	2.2 (1.1–4.7)	0.04
Applesauce	15/58 (26)	32/170 (19)	1.9 (0.8–4.2)	0.15
Pizza	20/55 (36)	47/172 (27)	1.6 (0.7–3.7)	0.29
Potato chips	22/58 (38)	81/167 (49)	0.7 (0.3–1.1)	0.27
Peanuts	11/61 (18)	63/166 (38)	0.3 (0.1–0.7)	0.004

\* Previously frozen chicken products included chicken nuggets, chicken strips, and other breaded or stuffed chicken products. Any peanut butter–containing product included jarred peanut butter and any baked or prepackaged food containing peanut butter. For previously frozen chicken products, 20% of case patients were missing exposure information; for all other variables, less than 10% of case patients and controls were missing information. CI denotes confidence interval.

and shipment of peanut butter and peanut paste at the Georgia facility; the PCA Texas facility ceased operations on February 10. Recalls expanded throughout the investigation, eventually encompassing all peanuts and peanut products processed at the PCA Georgia and Texas facilities since January 1, 2007 (Fig. 1). A total of 3918 peanut butter–containing products from over 200 companies were recalled between January 10 and April 29, 2009.<sup>16</sup>

## DISCUSSION

This nationwide outbreak of human *Salmonella* Typhimurium infections was linked to the eating of contaminated peanut butter, peanut paste, and roasted peanuts produced at the PCA facilities in Georgia and Texas. This outbreak resulted in one of the largest food recalls in U.S. history and an estimated \$1 billion loss in peanut sales.<sup>17</sup> Laboratory evidence indicated that cases might also be related to thousands of other food products containing PCA peanut paste and to freshly ground peanut butter made from PCA's roasted peanuts. Because many persons with salmonellosis do not seek medical care or are not tested, it is estimated that 16 times as many cases of illness occurred than were reported.<sup>1,18</sup>

This outbreak illustrates the challenge posed by ingredient-driven outbreaks. Many food items made with the same contaminated ingredient may be involved, each with separate distribution channels and consumer bases. The investigation of fo-

cal clusters of cases in institutional settings, especially reviewing invoices for foods common among institutions, and rapid trace-back of the suspected food to the point of manufacture provided critical clues in this outbreak. Even after brand X peanut butter was implicated and recalled, ongoing case-patient interviews by local and state health departments revealed that many cases could not be explained by consumption of brand X peanut butter and raised hypotheses about other possible peanut butter–containing vehicles. Trace-back and trace-forward findings, product testing, and a second case–control study were crucial to identifying other contaminated peanut butter–containing products and to expanding recalls. After the recall of many products associated with the Georgia PCA facility, continued case-patient interviews by the Colorado Department of Public Health and Environment led to the implication of a product from the Texas PCA facility, which had not been previously linked to the outbreak. These findings highlight the need to continue interviewing case patients in an ongoing outbreak, even after one food vehicle has been implicated, and to continually refine hypotheses as more information is collected.

*Salmonella* contamination can occur during many stages of peanut butter production. *Salmonella* introduced in the soil through the addition of manure or through irrigation can survive for months to years, contaminating peanuts growing underground; further contamination may occur during peanut harvesting, transportation, or stor-

**Table 2. Odds Ratios of *Salmonella* Typhimurium Infection in Case Patients vs. Controls in 30 States in Study 2, January 17–19, 2009, According to Ingested Food Item or Other Exposure.**

Food Item or Exposure	Case Patients (N=95) <i>no./total no. (%)</i>	Controls (N=362) <i>no./total no. (%)</i>	Odds Ratio (95% CI)	Matched Exact Odds Ratio Adjusted for Age Group (95% CI)*
<b>Peanut butter</b>				
Peanut butter outside home	13/79 (16)	19/349 (5)	4.3 (1.7–10.6)	3.9 (1.6–10.0)
Peanut butter at home	44/91 (48)	214/354 (60)	0.6 (0.3–0.9)	0.5 (0.3–0.9)
Any peanut butter	64/84 (76)	221/340 (65)	1.6 (0.9–3.1)	1.5 (0.8–2.7)
Single-serving packets of peanut butter	3/89 (3)	5/354 (1)	2.2 (0.3–11.5)	2.9 (0.4–16.0)
<b>Peanut butter crackers</b>				
Any peanut butter crackers†	54/82 (66)	56/356 (16)	9.1 (4.9–18.1)	8.0 (4.2–16.2)
Brand A or B peanut butter crackers	42/82 (51)	21/356 (6)	13.0 (6.4–29.3)	13.1 (6.0–31.7)
Brand A peanut butter crackers	32/82 (39)	11/356 (3)	18.7 (7.6–55.1)	17.2 (6.9–51.5)
Brand B peanut butter crackers	13/82 (16)	12/356 (3)	4.1 (1.7–10.7)	3.6 (1.3–9.8)
<b>Other products</b>				
Roasted peanuts	10/89 (11)	113/350 (32)	0.2 (0.1–0.5)	0.3 (0.1–0.6)
Prepackaged peanut butter sandwiches	5/88 (6)	6/360 (2)	3.5 (0.8–15.6)	3.2 (0.6–17.6)
Peanut butter cereals‡	8/91 (9)	13/359 (4)	2.3 (0.8–6.1)	—
Ice cream or ice cream toppings with peanut butter	10/90 (11)	22/357 (6)	1.9 (0.8–4.5)	1.7 (0.7–4.1)
Peanut butter–containing sandwich-style cookies	6/88 (7)	14/362 (4)	1.8 (0.5–5.2)	1.3 (0.4–4.1)
Peanut butter candy	22/82 (27)	114/344 (33)	0.8 (0.4–1.5)	0.8 (0.4–1.4)
Nutrition bars with peanut butter	20/85 (24)	72/356 (20)	1.3 (0.7–2.4)	1.1 (0.5–2.1)
Peanut butter pet treats‡	2/91 (2)	14/354 (4)	0.6 (0.1–2.7)	—
Premade dough with peanut butter	3/87 (3)	8/360 (2)	1.6 (0.2–9.0)	1.1 (0.1–6.7)
Peanut butter non–sandwich-style cookies	12/86 (14)	51/352 (14)	0.9 (0.4–1.8)	0.9 (0.4–1.8)
Peanut butter–containing desserts‡	4/88 (5)	15/356 (4)	1.0 (0.2–3.4)	—
Pretzels with peanut butter	2/90 (2)	11/360 (3)	0.7 (0.1–3.6)	0.9 (0.1–4.7)
<b>Other</b>				
Attended an institution	45/94 (48)	127/359 (35)	1.9 (1.2–3.3)	1.4 (0.7–2.8)
Visited an institution‡	10/93 (11)	43/362 (12)	0.9 (0.4–1.9)	—

\* Age groups adjusted for were 0 to less than 6 years, 6 to less than 18 years, 18 to less than 40 years, and 40 years or older.

† Three brands of peanut butter crackers were not statistically associated with illness.

‡ Peanut butter cereals, pet treats, desserts, and visit to an institution were not included in multivariable analysis.

age by means of exposure to animal droppings or soil or water from transport equipment.<sup>19</sup> During commercial peanut butter production, peanuts are typically roasted at approximately 350°F (180°C), a temperature that should kill salmonella.<sup>20</sup> As roasted peanuts are ground into peanut butter, grinding generates heat of 71 to 77°C for approximately 20 minutes, which is not sufficient

to kill salmonella.<sup>21,22</sup> Therefore, salmonella introduced after initial peanut roasting can survive.<sup>23</sup>

The ultimate cause of contamination in this outbreak is unknown; at the Georgia PCA facility, rainwater leakage into storage areas, storage of raw peanuts near roasted peanuts, and possibly inadequate peanut roaster temperatures suggest that salmonella may have arrived on raw peanuts



or was introduced in the facility and survived processing. Since peanuts and peanut products were transferred between the Texas and Georgia facilities, both of which had inadequacies on inspection, it is not possible to say where the contamination originated.

Salmonella can survive in a low-moisture food such as peanut butter for at least 24 weeks<sup>24</sup>; therefore, if postprocessing contamination occurs, salmonella may survive in peanut butter for its entire shelf life of 18 to 24 months.<sup>24-26</sup> Salmonella has caused long-lasting and highly distributed outbreaks in other low-moisture foods.<sup>24,27</sup> However, lack of moisture in food prevents multiplication, so large focal outbreaks related to the mishandling of these foods in one location are unlikely. Contamination of low-moisture foods is likely to lead to prolonged, dispersed outbreaks that may be sustained as long as production conditions lead to contamination. The duration of the outbreak and range of production dates among salmonella-positive food samples suggest that the outbreak strain may have been present in the PCA facilities for an extended period.

The complex nature of this outbreak led to an iterative investigative approach (see the Supplementary Appendix). The first vehicle implicated, brand X peanut butter, was sold to institutions only and thus could not be specifically identified by patients, making it impossible to assess exposure without also reviewing institutional invoices. Questions about peanut butter consumption likely elicited information about peanut butter eaten at home rather than at institutional facilities. Study 2 implicated peanut butter eaten outside the home as well as a general preference for eating peanut butter and peanut butter-containing products, but subjects could not recall brand names. The initial link between brand X peanut butter and the PCA was critical to uncovering connections among the other contaminated peanut-containing products. Since PCA peanut paste was an ingredient in thousands of diverse products including human food and pet food products, it was difficult to identify

a specific suspect vehicle during hypothesis generation and in the case-control studies. Although study 2 had sufficient power to implicate peanut butter crackers, it had limited power to implicate other individual products that most likely accounted for only a few cases.

This outbreak was instrumental in refocusing national attention on food safety and spurring discussions about gaps in the food safety system and methods for establishing and enforcing basic preventive controls. The White House Food Safety Working Group was created in March 2009 to identify actions to improve foodborne disease prevention and strengthen surveillance and regulatory authority.<sup>28</sup> One such action was the launch of the FDA's Reportable Food Registry, which requires food industry officials to alert the FDA within 24 hours after the discovery that a food product has a reasonable probability of causing adverse health consequences in humans and animals; the registry is meant to enhance the FDA's ability to act quickly to prevent foodborne illness.<sup>29</sup> In the first 6 months after its launch, the Reportable Food Registry received 125 primary reports from industry and regulatory officials about 25 commodities; of these, 37% concerned salmonella contamination.<sup>30</sup> The Food Safety Modernization Act, signed into law January 4, 2011, is a positive step toward transforming the food safety system. Under the law, for the first time, the FDA has the authority to mandate food recalls, stop distribution of unsafe food, and require prevention-based food safety plans from domestic and foreign food suppliers<sup>31,32</sup>; these actions are vital to preventing foodborne illness outbreaks.

A successful food safety system for the future depends on adequate resources to ensure implementation of the Food Safety Modernization Act and continuing collaboration among regulatory authorities, state and federal public health experts, and industry officials.

Disclosure forms provided by the authors are available with the full text of this article at [www.nejm.org](http://www.nejm.org).

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