

A Novel Vehicle for Transmission of *Escherichia coli* O157:H7 to Humans: Multistate Outbreak of *E. coli* O157:H7 Infections Associated With Consumption of Ready-to-Bake Commercial Prepackaged Cookie Dough—United States, 2009

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Background. *Escherichia coli* O157:H7 is a Shiga toxin–producing *E. coli* (STEC) associated with numerous foodborne outbreaks in the United States and is an important cause of bacterial gastrointestinal illness. In May 2009, we investigated a multistate outbreak of *E. coli* O157:H7 infections.

Methods. Outbreak-associated cases were identified using serotyping and molecular subtyping procedures. Traceback investigation and product testing were performed. A matched case-control study was conducted to identify exposures associated with illness using age-, sex-, and state-matched controls.

Results. Seventy-seven patients with illnesses during the period 16 March–8 July 2009 were identified from 30 states; 35 were hospitalized, 10 developed hemolytic-uremic syndrome, and none died. Sixty-six percent of patients were <19 years; 71% were female. In the case-control study, 33 of 35 case patients (94%) consumed ready-to-bake commercial prepackaged cookie dough, compared with 4 of 36 controls (11%) (matched odds ratio = 41.3; $P < .001$); no other reported exposures were significantly associated with illness. Among case patients consuming cookie dough, 94% reported brand A. Three nonoutbreak STEC strains were isolated from brand A cookie dough. The investigation led to a recall of 3.6 million packages of brand A cookie dough and a product reformulation.

Conclusions. This is the first reported STEC outbreak associated with consuming ready-to-bake commercial prepackaged cookie dough. Despite instructions to bake brand A cookie dough before eating, case patients consumed the product uncooked. Manufacturers should consider formulating ready-to-bake commercial prepackaged cookie dough to be as safe as a ready-to-eat product. More effective consumer education about the risks of eating unbaked cookie dough is needed.

Escherichia coli O157:H7 and other Shiga toxin–producing *E. coli* (STEC) strains are an important cause of bacterial gastrointestinal illness in the

United States. Illness can be severe, especially in young children or the elderly, and hemolytic-uremic syndrome (HUS) occurs in 4%–13% of patients [1]. *E. coli* O157 infection is the most common cause of HUS in children [2, 3].

Since the mid-1990s, *E. coli* O157 has been associated with >180 reported foodborne outbreaks in the United States [4]. Ground beef, leafy green vegetables, and unpasteurized dairy products have been frequently implicated in outbreaks [4–12]. Other implicated foods include sprouts, unpasteurized apple cider, melons and

Received 15 June 2011; accepted 4 October 2011; electronically published 8 December 2011.

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Clinical Infectious Diseases 2012;54(4):511–8

Published by Oxford University Press on behalf of the Infectious Diseases Society of America 2011.

DOI: 10.1093/cid/cir831

other fruits, and salami [4, 13–15]. Direct animal contact, drinking or swimming in contaminated water, contaminated environments, and person-to-person transmission have also been linked with outbreaks [16–22].

The reservoir for *E. coli* O157 is the intestinal tract of healthy ruminant animals (eg, cattle, deer, goats, and sheep). Foods typically are contaminated through the slaughter of colonized cattle and beef processing, shedding of pathogens from colonized cattle into milk, use of contaminated soil or contaminated irrigation water in produce production, or cross-contamination. Because kill steps are often used in food processing, processed foods containing cooked meat or produce are thought to be at lower risk for contamination.

We report the investigation of a multistate outbreak of *E. coli* O157 infections that identified a novel vehicle for foodborne transmission of STEC to humans: ready-to-bake commercial prepackaged cookie dough.

METHODS

Detection of the Outbreak

On 19 May 2009, PulseNet, the national molecular subtyping network for foodborne disease surveillance, identified a cluster of 17 cases of *E. coli* O157:H7 infections with indistinguishable pulsed-field gel electrophoresis (PFGE) patterns (*Xba*I: EXHX01.0224/*Bln*I: EXHA26.0536) submitted from 13 states. All 17 isolates were submitted in May, exceeding the baseline average of 6–7 isolates submitted each month from 2004 to 2008. State and local public health officials and the Centers for Disease Control and Prevention (CDC) initiated a multistate investigation of the outbreak.

Case Definition

A case was defined as diarrheal illness with onset from 1 March 2009 to 31 July 2009 in a US resident yielding the outbreak strain: *E. coli* O157:H7 or *E. coli* serotype pending with PFGE pattern *Xba*I: EXHX01.0224/*Bln*I: EXHA26.0536 and either a multiple-locus variable-number tandem repeat analysis (MLVA) pattern indistinguishable from the primary MLVA outbreak pattern or a MLVA pattern differing at a single locus (of 8) by 1 repeat from the primary MLVA pattern.

Case Finding

PulseNet was used to detect cases; CDC also queried international PulseNet databases in Canada, Latin America, and the Caribbean. PFGE of human *E. coli* O157 isolates was performed at PulseNet-affiliated public health laboratories using standardized methods [23]. PFGE patterns were submitted to the national PulseNet database and compared. Isolates with PFGE patterns indistinguishable from the first 17 isolates were sent to CDC for MLVA testing using standardized protocols [24].

Hypothesis Generation

Investigators used an iterative approach to generate hypotheses about the exposure vehicle. Early in the investigation, investigators in several states interviewed patients or their proxies with enteric disease questionnaires. A standardized targeted questionnaire was administered to patients; this questionnaire focused on exposures commonly associated with previous *E. coli* O157 outbreaks, including ground beef, raw dairy products, leafy green vegetables, and animal contact. Later in the investigation, when a clear hypothesis had not emerged, a single interviewer conducted conversational open-ended interviews with 5 patients from Washington State to obtain detailed qualitative exposure histories and identify unusual exposures.

Case-Control Study

To test exposure hypotheses, the investigation team conducted a matched case-control study. Controls were enrolled from state health department databases containing patients with non-*E. coli* enteric illnesses (eg, *Salmonella*, *Campylobacter*), starting with the most recently reported and working backward in time by onset date; persons reporting international travel during the time period of interest (the week before onset of illness in the matched case patient) were not eligible to be controls. Controls were matched 1:1 with case patients by age group (1–4 years, 5–14 years, 15–19 years, 20–39 years, 40–59 years, ≥60 years), sex, and state of residence.

The study questionnaire focused on 20 food items identified during hypothesis generation, including ready-to-bake cookie dough, ground beef, strawberries, apples, cantaloupe, and chocolate chips. The questionnaire also solicited brand and other detailed product information. Verbal consent from parents or guardians was obtained before interviews with persons <18 years of age; parents or guardians were interviewed as proxies for all children <15 years of age. State and local public health officials administered the questionnaire by telephone.

Data from questionnaires were entered into an electronic database. SAS 9.1 software (SAS Institute) was used to calculate matched odds ratios (ORs), exact 95% confidence intervals (CIs), and exact *P* values. A *P* value of ≤.05 was considered statistically significant.

Traceback and Environmental Investigation

Product information, including lot numbers and use-by dates (UBDs), from packages of epidemiologically implicated foods obtained from case patient households were provided by state investigators and the CDC to the US Food and Drug Administration (FDA) for traceback investigations. FDA inspected 2 facilities (plants A and B) involved in the manufacture of the implicated food product and tested samples collected from closed packages of retained finished product, product linked to consumer complaints, raw ingredients used to make the implicated product, in-line production samples, water samples, and

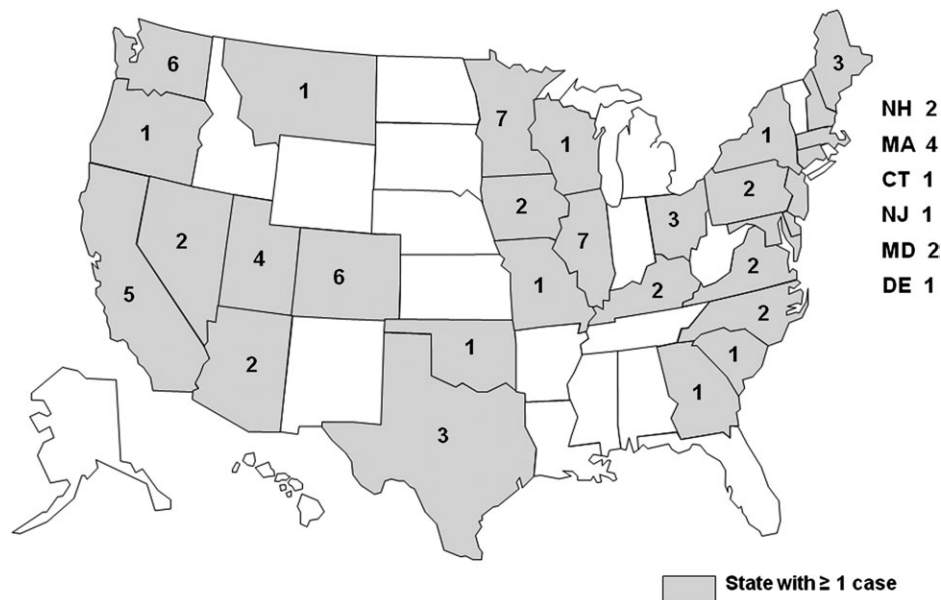


Figure 1. Outbreak-associated *Escherichia coli* O157 cases by state of residence, United States, 1 March–31 July 2009 (n = 77).

environmental samples. FDA investigators also inspected a mill supplying flour to plant A (mill A); samples from the mill and its premises (eg, wheat storage areas) were also collected.

Product Testing

Testing of opened packages of implicated food product collected from patient residences and unopened packages from retail stores was performed by investigators at 11 public health laboratories (local, state, and CDC) and 1 private laboratory that works with a state health department. FDA laboratories tested product collected during inspections of manufacturing facilities. Testing protocols for *E. coli* O157:H7 and other STEC strains varied by laboratory; culture and several other methods were used, including immunomagnetic separation, polymerase chain reaction, Shiga toxin (Stx) enzyme immunoassay, and O157 latex agglutination. State public health laboratories performed PFGE and Stx testing on STEC isolated from open product. STEC isolated by FDA laboratories was sent to CDC for PFGE and Stx testing. *E. coli* O157:H7 isolates were sent to CDC for MLVA testing [24].

RESULTS

Case Patients

Seventy-seven cases from 30 states met the case definition (Figure 1); illness onsets ranged from 16 March 2009 to 8 July 2009 (Figure 2). The median age of patients was 15 years (range, 2–65 years); 66% were <19 years of age. Seventy-one percent were female. Patients aged 5–19 years comprised 55% of patients, and females predominated in all but 1 age group (Figure 3). Thirty-five of 64 (55%) patients with available information were

hospitalized and 10 of 57 (18%) developed HUS; none died. No outbreak-associated infections were identified outside the United States. Of 21 cases with Stx test results, 19 were positive for Stx 2 only, 1 for both Stx 1 and 2, and 1 was Stx positive, type undetermined.

Hypothesis Generation

Review of general enteric and targeted questionnaires available on 12 June 2009 revealed that consumption of several food items were reported at relatively high frequency ($\geq 70\%$) among case patients: poultry, strawberries, ground beef, apples, and leafy greens or lettuce (patients reported a variety of lettuce types). Prepackaged lettuce, spinach, sprouts, melons, unpasteurized dairy products, apple cider, and pepperoni/salami were each reported by <40% of patients.

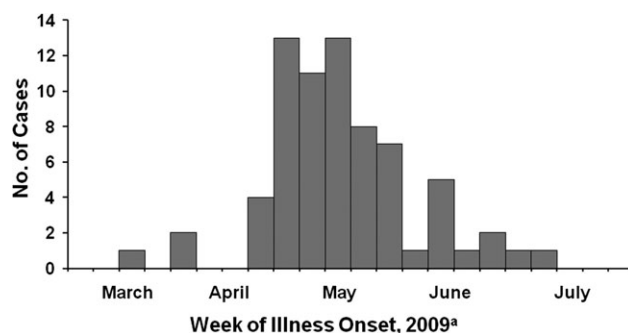


Figure 2. Outbreak-associated *Escherichia coli* O157 cases by week of illness onset, United States, 1 March–31 July 2009 (n = 70)^a. ^aOnset date missing for 7 patients.

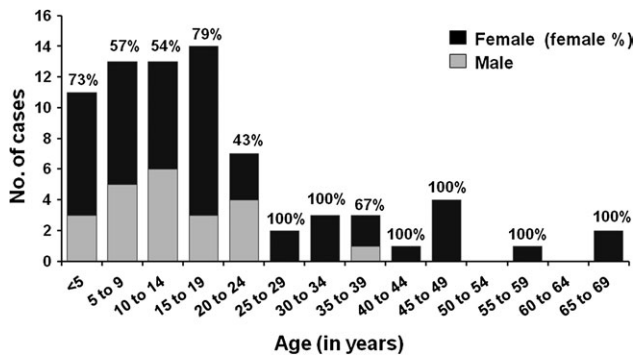


Figure 3. Outbreak-associated *Escherichia coli* O157 case patients by age and sex, United States, 1 March–31 July 2009 (n = 74)^a. ^aAge missing for 1 patient and sex missing for 2 patients.

During open-ended interviews conducted 13–16 June with 5 Washington patients, all reported consumption of ready-to-bake commercial prepackaged cookie dough (“cookie dough”). Four reported consuming brand A cookie dough. These data were presented to the investigative team, and investigators from several other states reported that patients mentioned eating cookie dough during earlier interviews.

Case-Control Study

From 17 to 19 June 2009, 36 case patients and 36 matched controls from 18 states were enrolled into the matched case-control study. Cookie dough consumption was the only reported exposure significantly associated with illness: 33 of 35 case patients (94%) versus 4 of 36 controls (11%) reported consuming cookie dough during the 7 days before illness onset (matched OR = 41.3 [95% CI, 7.37–>999.99]; $P < .001$) (Table 1). Brand A cookie dough consumption was reported by 31 of the 33 case patients (94%) who reported cookie dough consumption. Among these 31 patients, 26 (84%) consumed solely a chocolate chip variety, 3 (10%) consumed chocolate chip and another flavor, and 2 (6%) did not know the flavor; none reported consuming only a non-chocolate chip flavor. None of the 4 controls reporting cookie dough consumption named brand A cookie dough.

Traceback and Environmental Investigation

Based on the evidence from the epidemiologic investigation, FDA conducted a traceback of brand A cookie dough products. UBDs from 4 open packages of brand A cookie dough from patients’ homes ranged from 23 June to 11 August 2009. Plant A manufactured all but 2 varieties of brand A cookie dough; the remaining 2 were manufactured at plant B, located in another state. Product from plant A was shipped to many locations throughout the United States; no product from this plant was shipped to Canada or other countries. Brand A represented approximately 40% of the US prepared cookie dough market [25].

An FDA inspection team inspected plant A during 18 June–9 July 2009. Cultures of all ingredients, in-line production, water, and environmental samples collected from the plant and tested by FDA failed to yield *E. coli* O157. The FDA did not identify a source, vehicle, or production process that contributed to *E. coli* contamination of the cookie dough at plant A. In addition, FDA did not substantiate any link between flour mill A or plant B and the outbreak; cultures of environmental samples from mill A were negative for *E. coli* O157, although a non-O157 STEC (O26:H11, Stx 1) was isolated from animal droppings found on mill grounds.

Product Testing

One hundred sixty-one samples of brand A cookie dough were tested; 157 of these were unopened market samples with UBDs ranging from 15 April 2009 to 29 September 2009. All 157 were negative for *E. coli* O157. Four samples of open product from confirmed case-patient residences in Minnesota, New York City, Oklahoma, and Washington were tested. All 4 were negative for *E. coli* O157, but 2 yielded Stx 2–producing non-O157 STECs: *E. coli* O8:H19 from product purchased in Minnesota (UBD: 23 June 2009) and *E. coli* O8,O60:H7 from product purchased in New York City (UBD: unknown).

FDA tested 50 product samples associated with the plant A inspection in 5 laboratories: 46 retained finished product samples and 4 samples linked to consumer complaints. One retained sample with a UBD of 10 June 2009 (manufactured 10 February 2009) yielded *E. coli* O157:H7 (Stx 2); all other samples cultured were negative for any STEC. Testing performed by CDC revealed that the *E. coli* O157:H7 isolate from the retained sample had a different PFGE and MLVA pattern than the outbreak strain. No human isolates submitted to PulseNet in 2009 had PFGE patterns matching those of the food sample STEC isolates.

Product Recall and Public Health Impact

Company A halted cookie dough production at plant A on 18 June 2009. On 19 June 2009, company A voluntarily recalled all brand A cookie dough products [26], which included 47 products and 3.6 million packages of cookie dough. On 7 July 2009, after implementing an enhanced ingredient, product, and environmental testing program, company A restarted cookie dough production at plant A [27]. Packaging was relabeled to display more prominent warnings against consuming unbaked cookie dough. On 13 January 2010, company A announced that 2 additional samples of finished product had tested positive for nonoutbreak strains of *E. coli* O157:H7 under its testing program; no product had been shipped to stores [28]. Company A also announced plans to convert to using heat-treated flour in cookie dough production during the week of 25 January 2010 to enhance product safety [28].

Table 1. Reported Frequency of Food Item Consumption by Case Patients and Controls Included in the Matched Case-Control Study, 17–19 June 2009^a

Food Item Exposure	Cases (n = 36) ^a , No. (%)	Controls (n = 36) ^a , No. (%)	Matched OR (95% CI)	P Value
Ready-to-bake cookie dough ^b	33 (94) ^b	4 (11)	41.3 (7.37–>999.99)	<.001
Ready-to-bake cookie dough, chocolate chip variety ^c	30 (94)	3 (9)	37.0 (6.56–>999.99)	<.001
Chocolate chips, other ^d	6 (30)	12 (34)	0.8 (.16–3.72)	1.00
Ground beef	27 (87)	26 (74)	3.5 (.67–34.53)	.18
Strawberries	18 (60)	14 (40)	2.2 (.70–8.08)	.21
Ice cream/frozen desserts not containing cookie dough	11 (69)	26 (79)	0.3 (.01–2.53)	.38
Hotdogs	7 (44)	15 (50)	0.5 (.08–2.34)	.51
Bologna	3 (17)	7 (21)	0.5 (.05–3.49)	.69
Mandarin oranges	2 (11)	6 (17)	0.5 (.05–3.49)	.69
Smoothies	2 (11)	5 (14)	0.5 (.05–3.49)	.69
Bacon	10 (56)	10 (29)	1.7 (.32–10.73)	.73
Raw carrots	9 (47)	17 (49)	0.7 (.14–2.81)	.75
Fruit Roll-Ups	9 (26)	6 (18)	1.5 (.36–7.23)	.75
Apples	18 (67)	19 (58)	1.4 (.38–5.59)	.77
Cantaloupe	5 (26)	6 (17)	1.3 (.23–9.10)	1.00
Cucumbers	7 (35)	13 (38)	0.8 (.11–4.43)	1.00
Grapes	12 (60)	17 (50)	1.0 (.27–3.74)	1.00
Milk	20 (91)	29 (81)	2.0 (.10–117.99)	1.00
Raspberries	3 (14)	5 (14)	1.0 (.07–13.80)	1.00
Smoothies from smoothie shop	2 (11)	2 (6)	1.0 (.07–13.80)	1.00
Watermelon	5 (25)	6 (18)	1.5 (.17–17.96)	1.00

Abbreviations: CI, confidence interval; OR, odds ratio.

^a Denominator for case patients ranged from 16 to 35, and denominator for controls ranged from 30 to 36 and was dependent on how many provided information on a particular exposure; matched case patients and controls were from 18 states.

^b Consumption of ready-to-bake commercial prepackaged cookie dough. One case reported “maybe” to raw cookie dough consumption and was excluded from the analysis for this variable (n = 35).

^c Consumption of chocolate chips in a chocolate chip variety of ready-to-bake commercial prepackaged cookie dough. Variable created for analysis based on cookie dough flavors reported by study participants.

^d Chocolate chips that were not consumed as part of brand A cookie dough (ie, consumed in homemade products using chocolate chips, non-brand A baked chocolate chip cookies, chocolate chip ice cream, granola bars).

DISCUSSION

We report a nationwide outbreak of *E. coli* O157 infections associated with consumption of ready-to-bake commercial prepackaged cookie dough. This outbreak is the first time ready-to-bake commercial prepackaged cookie dough or a similar product has been implicated as a vehicle for STEC infections. The case-control study found a strong association between consumption of ready-to-bake cookie dough and illness, and patients almost exclusively reported consuming brand A chocolate chip cookie dough disproportionate to the brand’s market share. The geographic distribution of cases and the product distribution aligned with the epidemiologic findings: no product was shipped to Canada or any other country, and no cases were identified outside the United States. In addition, STEC strains were obtained from the product, revealing that STEC can contaminate and survive in these processed products. There was no evidence to suggest that the nonoutbreak strains of STEC

recovered from cookie dough were linked to human infections. The strong epidemiologic evidence implicating brand A cookie dough as the vehicle for the infections led to a voluntary nationwide recall of all brand A cookie dough.

Despite extensive traceback and environmental investigations and testing by regulatory agencies and company A, the source and route of product contamination remains undetermined. Possible means of contamination include introduction of a contaminated ingredient during processing, a lapse in plant biosecurity measures, intentional contamination, or cross-contamination with another food processed in the plant. Although the manufacturing plant is located in a rural area in the mid-Atlantic United States, investigators did not observe any obvious breach in biosecurity that would facilitate introduction of *E. coli* O157 into the facility from the outside. No significant food handling or safety violations were identified at the plant that could result in cross-contamination within the plant. Intentional contamination of food with

pathogens has been linked to past local, but not national, foodborne outbreaks [29–31]. Although the possibility of intentional contamination was considered early in the investigation, no evidence of it was found.

A more likely source of contamination is that a contaminated ingredient was used in the product. Ready-to-bake cookie dough is not a ready-to-eat food and contains several ingredients, including flour, pasteurized eggs, chocolate chips, molasses, sugar, margarine, baking soda, and vanillin/vanilla extract. The eggs used in brand A products were pasteurized, making eggs a less likely vehicle unless there was a pasteurization failure; this was not identified during the investigation. Molasses, sugar, baking soda, and margarine, which undergo pathogen kill steps during processing, were also considered less likely sources of contamination.

The possibility of contaminated chocolate chips was considered, because most patients reported consuming chocolate chip-containing varieties of brand A cookie dough. Although chocolate has never been linked to past *E. coli* O157 outbreaks, it has been implicated in *Salmonella* outbreaks [32–34], and Baylis et al [35] documented survival of *E. coli* O157 in artificially contaminated chocolate for up to 366 days. However, because chocolate chip varieties comprise the majority of cookie dough sales, it would not be unusual that chocolate chip varieties were reported by most patients. The chocolate chips that company A uses in its ready-to-bake cookie dough and the brand A chocolate chips sold to consumers for home baking are manufactured in the same facility, but there was no evidence of an *E. coli* O157 outbreak among consumers using these chocolate chips. Study results also support that chocolate chips were not the source of contamination: consumption of a chocolate chip variety of cookie dough was less strongly associated with illness compared with consumption of any cookie dough, whereas consumption of chocolate chips in non-cookie dough products was not significantly associated with illness.

Flour, a raw agricultural product (ie, does not undergo processing to kill pathogens), was also considered as a possible source of contamination. Low levels of *Salmonella* contamination can occur in wheat flour, and flour and flour-based mixes have been implicated in foodborne *Salmonella* outbreaks [36–39]. Generic *E. coli* species have also been found in flour [36, 39]; 1 US study found *E. coli* in 12.8% of commercial wheat flour samples examined [39]. Although our investigation found no conclusive evidence that contaminated flour was the source of this outbreak, contaminated flour remains a prime suspect for introducing the pathogen to the product. Because flour is frequently purchased in large quantities by manufacturers for use in food products, if contaminated flour were responsible, a single purchase of contaminated flour might have been used to manufacture multiple lots and varieties of dough over a period of time. This would be consistent with UBDs on packages obtained from patients

(23 June–11 August 2009), suggesting that product contamination occurred over several weeks.

This outbreak highlights the consequences of risky eating behaviors among consumers, specifically the health risks associated with eating unbaked products that are intended to be cooked before consumption. Consumption of cookie dough appears to be a popular practice, especially among adolescent females. A study of risky eating behaviors among college students revealed that 53% consumed unbaked homemade cookie dough [40]. In our case-control study, 11% of controls reported eating cookie dough. During interviews, several patients reported that they bought the dough with the intention of only eating it unbaked; they had no plans to actually bake cookies. More effective public health messaging is needed to educate consumers about the health risks of this practice and encourage behavior change that will prevent illnesses such as those described in this report.

Linking this type of processed food product to an outbreak of *E. coli* O157 infections has implications for the food industry and emphasizes that the possibility of contamination of processed ready-to-cook and ready-to-bake foods by human pathogens remains an ongoing risk to public health. The FDA has been advised by several cookie dough manufacturers that they have implemented the use of heat-treated flour for their ready-to-bake cookie dough products. However, all manufacturers should consider formulating ready-to-bake commercial pre-packaged cookie dough to be as safe as a ready-to-eat food item. Foods containing raw flour should be considered as possible vehicles of infection of future outbreaks of STEC or *Salmonella* infections. Food processors should consider the use of pasteurized flour in ready-to-cook or ready-to-bake foods that are likely to be consumed without cooking or baking, even though label statements may warn against consuming uncooked product.

Notes

Acknowledgments. The authors thank the following local, state, and federal public health and regulatory officials for their contributions to the epidemiologic, laboratory, and environmental investigations during this outbreak: Arizona: Joli Weiss and Clarisse Tsang; Arkansas: Linda Gladden; California: Akiko Kimura, Jeffrey Higa, Bela Matyas, Dawn Norton, Amy DuBois, Sara Cody, Laura Tang, Barbara Baldwin, Lou Anne Cummings, Jeff Farrar, Benson Yee, Pat Kennelly, Will Probert, Janice Lidgard, Sharon Crowley, Annie Kao, and Ali Fernandez; Colorado: Alicia Cronquist and Nicole Comstock; Connecticut: Quyen Phan and Sharon Hurd; Delaware: Susan Shore; Florida: Kathleen VanZile; Georgia: Cherie Drenzek and Hope Dishman; Idaho: Chris Hahn and Leslie Tengelson; Illinois: Connie Austin and Laurie Saathoff; Iowa: Ann Garvey, Diana VonStein, Meghan Harris, Gina Kline, and Larry Holcomb; Kentucky: Robert Brawley, Tracy Vaughn, and Sandy Kelly; Maine: Vicki Rea; Maryland: Alvina Chu, Amanda Palmer, and David Blythe; Massachusetts: Barbara Bolstorff, Emily Harvey, and Franny Elson; Michigan: James Collins, Katie Sheline, Sally Bidol, and Susan Bohm; Minnesota: Kirk Smith, Carrie Rigdon, Matt Forstner, Selina Jawahir, Fe Leano, and Charlott Taylor; Missouri: Jo Ann Rudroff and Harvey Marx; Montana: Howard Reid; Nebraska: Alison Keyser Metobo;

New Jersey: Kelly Miller, Lisa McHugh, and Michelle Malavet; New Hampshire: Elizabeth Daly; New York City: Heather Hanson; Nevada: Virginia Chiu, Devin Barrett, Richard Sowadsky, and Linda Verchick; North Carolina: David Bergmire-Sweat and Lorri Taylor; Ohio: Scott Nowicki; Oklahoma: Laurence Burnsed; Oregon: Hillary Booth, Julie Hatch, and William Keene; Pennsylvania: George Han and Andre Weltman; South Carolina: C. P. Kanwat and Julie Schlegel; Texas: Linda Gaul and Venessa Cantu; Utah: Marilee Poulson; Virginia: Jun Yang and Seth Levine; Washington: Erin Chester; West Virginia: Suzanne Wilson; Wisconsin: James Mack, John Archer, and Rachel Klos; CDC Division of Foodborne, Waterborne, and Environmental Diseases: Cheryl Bopp, Peter Gerner-Smidt, Gerardo Gomez, Mike Hoekstra, Mike Humphrys, Patricia Lafon, Michele Parsons, Deborah Talkington, Patricia Griffin, Ian Williams, and Rob Tauxe; US Food and Drug Administration: Morris Potter; US Department of Agriculture: Kristen Holt.

The findings and conclusions in this study are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

Potential conflicts of interest. All authors: No reported conflicts.

All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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