

Despite gaps in findings, flour fingered in 2009 cookie dough outbreak

ATLANTA — Contaminated wheat flour “remains a prime suspect” for causing an illness outbreak in connection with consumption of contaminated raw cookie dough in 2009, according to a study published Dec. 8 in *Clinical Infectious Disease*.

The report, written by a team led by Karen P. Neil of the Centers for Disease Control and Prevention in Atlanta, offers a detailed review of the outbreak. The researchers called it the first reported STEC (Shiga toxin-producing *E. coli*) outbreak associated with consuming ready-to-bake commercial prepackaged dough.

While fingering flour as the prime suspect, the authors acknowledged a failure by the Food and Drug Administration to “substantiate any link” between the outbreak and flour mills that supplied flour for the dough. Ultimately, the investigators never found traces of the *E. coli* that afflicted the patients in any dough product samples, either at stores or at patients’ homes.

The study brings together details of the 2009 outbreak that had come out at the time in bits and pieces or had not been previously released at all.

The outbreak came to light in May 2009 when PulseNet, the national molecular subtyping network for foodborne disease surveillance, identified a cluster of 17 cases of *E. coli* O157:H7 infections with indistinguishable genetic patterns, submitted from 13 states. As a result, state and local governmental agencies and the C.D.C. launched a multi-state investigation.

Patients initially were asked about consumption of food commonly associated with previous *E. coli* O157 outbreaks — 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 five patients from Washington state to obtain detailed qualitative exposure histories and identify unusual exposures,” the researchers said.

According to the study, while more than 70% of the larger survey group had consumed poultry, strawberries, ground beef, apples, and leafy greens or lettuce, all five of the Washington

patients reported consumption of ready-to-bake prepackaged cookie dough. Subsequently, 33 of the 35 patients who became sick said they had consumed unbaked cookie dough.

Overall, the outbreak resulted in 77 patients identified with illnesses between March 16 and July 8, 2009. The illnesses occurred in 30 states and resulted in 35 hospitalizations. Ten developed hemolytic-uremic syndrome, and none died.

H.U.S., which primarily affects



children and may cause kidney failure and low blood platelet counts, has a mortality rate ranging from 5% to 10%. Survivors generally recover without major consequences but a small percentage develop chronic kidney disease and depend on renal replacement therapy.

Two thirds of the patients were younger than 19, and 71% were female.

The cookie dough, described in the study as “Brand A,” was identified at the time as the Toll House brand of Nestlé USA.

According to the study, the F.D.A. conducted a trace back of the cookie dough products, finding packages in patients’ homes with use-by-dates ranging from June 23 to Aug. 11, 2009. The researchers said the brand has a 40% share of the U.S. prepared cookie dough market.

“An F.D.A. inspection team inspected plant A during 18 June-9 July 2009,” the researchers said. “Cultures of all ingredients, in-line production, water, and environmental samples

collected from the plant and tested by F.D.A. failed to yield *E. coli* O157. The F.D.A. did not identify a source, vehicle or production process that contributed to *E. coli* contamination of the cookie dough at plant A.”

Failure to identify a source of contamination extended beyond the Nestlé plant.

“In addition, F.D.A. did not substantiate any link between flour mill A or plant B and the outbreak,” the researchers said. “Cultures of environmental samples from mill A were negative for *E. coli* O157, although a non O157 STEC was isolated from animal droppings found on mill grounds.”

The F.D.A. purchased 157 samples of brand A cookie dough, all of which tested negative for *E. coli* O157. Four samples of open product from confirmed case patient homes were tested and were negative for O157 but yielded other dangerous *E. coli*.

The study said the company halted cookie dough production June 18 and voluntarily recalled all cookie dough products the following day — 47 different products and 3.6 million packages of cookie dough.

Production resumed July 7 after the company implemented “an enhanced ingredient, product and environmental testing program,” the study said.

Packaging was redesigned to display more prominent warnings against eating raw cookie dough.

Six months later, the company said two more positive samples for O157:H7 were identified but that no product had been shipped to stores.

“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,” the study said.

In the discussion section of the study, the researchers said the investigation did not generate clear findings of origin for the outbreak.

“Despite extensive trace back and environmental investigations and testing by regulatory agencies and company A, the source and route of product contamination remains undetermined,” the authors said. “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.”

Noting that no evidence of

intentional contamination was found, the researchers offered extensive analysis of why they believed an ingredient, probably flour, was the source of contamination:

"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


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 (i.e., 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*

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— Research team led by Karen P. Neil of the Centers for Disease Control and Prevention in Atlanta

has never been linked to past *E. coli* O157 outbreaks, it has been implicated in *Salmonella* outbreaks, and Baylis et al 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



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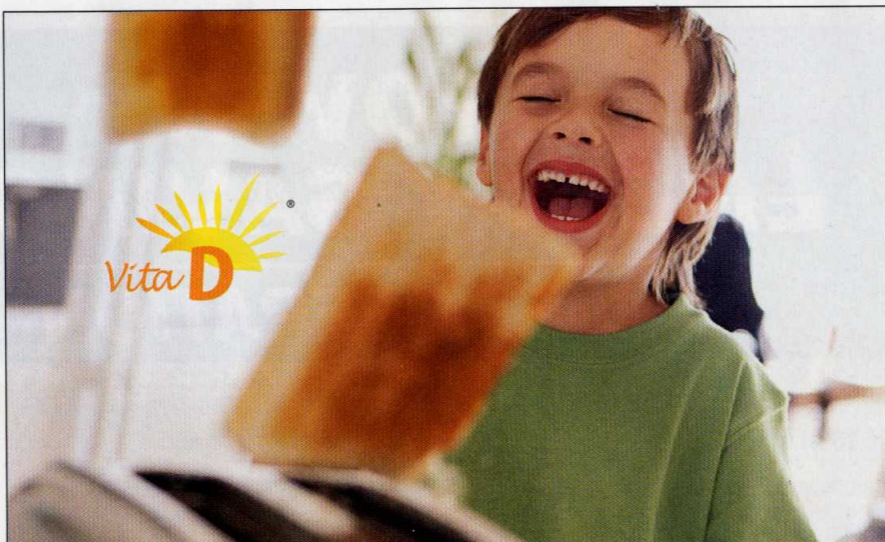
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outbreaks. Generic *E. coli* species have also been found in flour; one U.S. study found *E. coli* in 12.8% of commercial wheat flour samples examined. Although our investigation found no conclusive evidence that contaminated flour was the source of 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 (use-by dates) on packages obtained from patients (23 June–11 August 2009), suggesting that product contamination occurred over several weeks."

The researchers said the outbreak underscores the potential consequences of "risky eating behaviors," particularly eating unbaked products intended to be cooked before consumption.

"Consumption of cookie dough appears to be a popular practice, especially among adolescent females," the researchers said. They noted that several interviewed patients said they bought the dough with "the intention of only eating it unbaked; they had no plans to actually bake cookies."

They said more effective consumer education of these risks is needed.

The researchers ultimately concluded the study with a discussion of raw flour and steps taken by dough companies to avoid another outbreak.

"The F.D.A. 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," the researchers said. "However, all manufacturers should consider formulating ready-to-bake commercial prepackaged 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 products." MBN