Multistate Outbreak of *E. coli* O121 and O26 Associated with Raw Flour
FDA Post-Response and Outreach Activities

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Four CORE Functional Areas

- **Signals & Surveillance**
  - Detect Outbreaks

- **Response Team**
  - Stop Outbreaks

- **Post-Response**
  - Prevent Outbreaks

**Communications** informs the public
CORE Signals & Surveillance

- CORE notified of *E.coli* illness cluster on February 10, 2016
- Early investigation focused on produce and beef signals
- Interviews by CDC revealed signal for home baking and a particular flour brand
- CORE Signals transferred this outbreak to CORE Response Team 1 on April 7, 2016 for further coordination.
- At time of transfer to CORE Response, the case count was 31 cases from 17 states
<table>
<thead>
<tr>
<th>Recall Type</th>
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<th>Details</th>
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| Voluntary recall                | May 31, 2016          | • The firm recalls production dates: November 14, 2015 – December 4, 2015  
  • Approximately 10 million pounds of flour |
| 1st expanded voluntary recall   | July 1, 2016          | • Production date recall bracket: November 4, 2015 – December 4, 2015  
  • Expanded to approximately 30 million pounds  
  • Expansion impacted downstream recalls more than initial recall |
  • Based on firm’s own testing |
CORE Response Summary

• Convergence of epidemiologic, informational traceback, and microbiological analyses
• Dough or raw flour has been suspected before for STEC
• First time flour was confirmed as a vehicle in an outbreak
• Laboratory challenges – Atypical *E. coli* phenotype
  • Communication among FDA, CDC, and their respective laboratories led to identification of the atypical outbreak strain of STEC.
• Final case count: 63 with 17 hospitalizations in 24 states
Federal Public Messaging

2016

June 1
• FDA/CORE & CDC post outbreak and associated recall information

June 28
• FDA issued an expedited Consumer Update

June 28
• FDA posted a blog post co-authored by Drs. Steve Ostroff and Kathy Gensheimer telling the story of the outbreak investigation

July 1
• FDA/CORE & CDC update webposts to reflect recall expansion

July 25
• FDA/CORE & CDC update webposts to reflect additional expansion

July 27
• FDA issued a bulletin to restaurants and conducted outreach with the National Restaurant Association
Post-Response Trend Analysis

CORE Post Response analyzed data from the following four flour-related STEC outbreak investigations:

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<td>frozen food products</td>
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Flour/Dough Outbreak Analyses

**Epidemiological Data**
- Food vehicle
- Confirmed case-patient information
- Case-patient exposure routes

**Laboratory Data**
- Product sample information
- Product lab results
- Clinical lab results
- Outbreak strains

**Inspectional Findings**
- FDA observations
- Manufacturer findings

**Product Actions**
- Recalls
- Retail chain discontinued product use

**Communications**
- Public messaging
Analysis Findings

• Contrasting exposure routes
• Multi-ingredient dough products and dry flour
• Secondary exposure via handling
• 2 outbreaks in 2016 despite FDA’s advice to consumers and the retail industry after the 2009 and 2013 outbreaks
• Further efforts to inform consumer and retail industry needed
• Adequacy of product labeling
Inspectional Findings

• Cookie Dough/June 2009
  – Some equipment does not allow for proper cleaning
  – Firm’s root cause analysis

• Frozen food products/Feb 2013- (FSIS inspection)
  – Cooking instructions/validation for products is insufficient, and the product label may be confusing to customers.
  – Food Safety Assessment- firm had an inadequate hazard analysis, they failed to consider the potential of STEC in ingredients and finished product, and FSIS issued a “Notice of Intended Enforcement Action.”
Inspectional Findings

• Dry Dough Mix/Jan. 2016
  – Failure to maintain equipment in an acceptable condition through appropriate cleaning and sanitizing
  – Sanitizing agents are inadequate under conditions of use
  – Lack of backflow protection from piping systems that discharge waste water
  – Other observations included a lack of:
    • Microbiological testing at any point in their manufacturing process
    • Consistent hand washing after use of the restroom and again before returning to production.

• Flour/Feb 2016
  – No significant inspectional findings from all firms inspected
  – Firm’s root cause analysis
Messaging Recommendations

• Gather additional data regarding public perceptions of the risk of consuming and handling flour, raw and undercooked dough products.

• Expand FDA messaging regarding educational materials to advise retail food service industry, medical professionals, and consumers about the safe handling of raw dough and flour.
Collaborative Efforts

• Retail Food Protection Team
• Educational Outreach Branch - to expand consumer messaging
• Social Scientists - to develop and incorporate questions into the FDA Food Safety Survey to determine public perception of flour-associated risks
Retail Food Messaging

• Public messaging to retail establishments
• Targeted messaging to retail food stakeholders
  – Regional seminars – October 2017
  – Continue throughout 2018

Current Advice for Retailers

- Restaurants that allow their customers to handle raw dough should evaluate whether this practice is appropriate.
- Restaurants and retailers should be aware that flour may be a source of pathogens and should control the potential for cross-contamination of food processing equipment and the food processing environment.
Continued Outreach

• **FDA/CDC Publication:**

• **Numerous ProMED-mail posts:**
  - E. COLI EHEC - USA (37): RAW DOUGH, FDA ALERT
    - ****************************************************
  - ProMED-mail is a program of the
  - International Society for Infectious Diseases
  - <http://www.isid.org>
  - Date: Tue 28 Nov 2017
  - Source: FDA [edited]
Updated Consumer Updates

• **FDA Warns Against Consuming Raw Cookie Dough.** On its website, ABC News reports that the Food and Drug Administration warned people not to consume raw cookie dough because of the risks of consuming raw eggs and flour. Dr. Leslie Smoot, a senior advisor for the FDA’s Office of Food Safety, said in a statement, “Flour is derived from a grain that comes directly from the field and typically is not treated to kill bacteria.”
Home-made PlayDough! No!

- [Homemade PlayDough: A Simple and All-Natural Recipe - DIY Natural](https://www.diynatural.com › Health)
- Instructions. Mix together the **flour** and the salt. Mix together ½ cup of warm water with a few drops of food coloring. Slowly pour the water into the **flour** mixture, stirring as you pour. Stir until combined, then knead with your hands until the **flour** is completely absorbed.
- Jun 30, 2016 - Because consuming **contaminated flour** without cooking it first is a great way to get yourself some E. Coli, and that is a thing you do not want. ... Specifically, they advise against eating, handling, or **playing** with any raw **dough** or batter that contains **flour** in it at this time, and that’s a broad category — way ...
General Mills flour recall consumer information

- General Mills has recalled several types of flour due to *E. coli* illnesses the U.S. Food and Drug Administration and Centers for Disease Control and Prevention have linked to eating uncooked dough and batter made with raw flour.
- All products included in this recall are listed below.
- Illnesses have NOT come from properly baked or cooked flour.
- **Remember**
  Do not eat uncooked dough or batter made with raw flour. Flour is made from wheat that is grown outdoors where bacteria are often present. Flour is typically not treated to kill bacteria during the normal milling process.
- **Actions you should take**
- [Do not eat or taste](#) dough or batter made with raw flour.
Messaging for Prevention Efforts

Identification of Prevention Efforts for Outbreaks of Shiga Toxin-producing *Escherichia coli* Linked to Raw Dough, Undercooked Dough Products, and Flour

Tami Craig Cloyd, DVM; Cerisé Robinson, MPH; India James; Marianne Fatica, PhD; Sheila Pack Merriweather, MPH; Donald Obenhuber, PhD; Diane Gubermout, DrPH

*US Food and Drug Administration/ CORE Network, College Park, MD*

**Abstract**

Shiga toxin-producing *Escherichia coli* (STEC) O121, O26, and O157:H7 are foodborne pathogens that can cause human illness, including bloody diarrhea and hemolytic uremic syndrome. From 2006 to 2016, these bacteria have been associated with four outbreaks involving flour and raw or undercooked dough products. Outreach by FDA regarding these outbreaks involved informing consumers and retailers via web postings. The purpose of this study was to analyze the outbreaks of dough and flour-associated STEC infections, and identify additional prevention efforts. FDA's Coordinated Outbreak Response and Evaluation Network (CORE) collected and compared surveillance information, epidemiological and laboratory data, and established inspectional information from these four outbreaks. By analyzing this information, CORE identified similarities and differences among the outbreaks. Observed differences included the type of product (e.g., flour, raw cookie dough, and undercooked dough products) and routes of exposure. It was determined that contamination has the potential to occur not only in multi-ingredient dough products, but also in flour. The exposure routes in these outbreaks included consumption of raw cookie dough and undercooked dough products, as well as improper handling of raw dough at the consumer and retail food service levels. FDA issued web postings notifying the public of the recalls and informing consumers and the retail food service industry about the risk of consuming or improperly handling flour, raw dough, and undercooked dough products. These outbreaks provided evidence of STEC exposure via consumption or improper handling of flour and raw or undercooked dough products, and identified the need to further inform consumers and the retail food service industry about safe handling of these products. The outbreak information suggests that educational outreach and expanded consumer messaging may prevent another similar outbreak. In response to this documented health risk, CORE began evaluating prevention options and efforts to coordinate the development and implementation of prevention initiatives.

**Methods**

CORE Post Response analyzed data from the following four flour-related STEC outbreak investigations:

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Specific epidemiological information, laboratory data, inspectional findings, and product and regulatory actions from each of the four outbreaks were reviewed and compared. Similarities and differences of these data were analyzed to discover new information regarding STEC in flour outbreaks and identify additional prevention efforts.

**Introduction**

The Coordinated Outbreak Response and Evaluation Network (CORE), within the Food and Drug Administration (FDA), is a multidisciplinary organization established to coordinate and improve FDA's detection, response, and prevention efforts related to food safety and public health.

**Results**

The analysis revealed a trend in the case-patient exposure routes and the resulting FDA public messaging, via public web-postings. The differing exposure routes in these outbreaks included consumption of raw cookie dough and undercooked dough products, as well as improper handling of raw dough at the consumer and retail food service levels.

- **2009 outbreak of E. coli O157:H7 associated with cookie dough**
  - Involved consumption of prepackaged refrigerated cookie dough.
  - After this outbreak, FDA warned consumers of the risk of consuming or improperly handling raw dough, messaging was also included for food manufacturers and retailers.

- **2013 outbreak of E. coli O26 associated with undercooked dough**
  - Involved consumption of undercooked dough products.
  - After this outbreak, FDA advised consumers to handle dough and flour products carefully.

**Discussion/Conclusion**

The contrasting exposure routes of similar vehicles with flour as a common ingredient revealed that contamination has the potential to occur in mixes not multi-ingredient dough products, but also in flour. In addition, the reported exposure routes revealed that secondary exposure may occur via handling raw dough in addition to consuming the raw and undercooked dough products. Furthermore, two additional outbreaks occurred in 2016 involving undercooked dough products and flour: despite FDA's advice to consumers and the retail food service industry after the 2009 and 2013 outbreaks.

- **2015 outbreak of E. coli O26 associated with pizza dough**
  - Involved consumption of prepackaged refrigerated pizza dough.
  - After this outbreak, FDA advised consumers to handle pizza dough products carefully.

- **2016 outbreak of E. coli O157:H7 associated with undercooked dough**
  - Involved consumption of undercooked dough products.
  - After this outbreak, FDA advised consumers to handle dough and flour products carefully.
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  o Baltimore
  o Denver
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• FDA/CFSAN
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  o Office of Regulatory Science
  o Office of Compliance
  o Office of Analytics and Outreach
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  o Arizona
  o California
  o Colorado
  o Indiana
  o Maryland
  o Michigan
  o Minnesota
  o Oklahoma
  o Virginia
  o Washington
• FDA Coordinated Outbreak Response and Evaluation Network
  o CORE Signals & Surveillance
  o CORE Response Team 1
  o CORE Post-Response
    • Dr. Tami Cloyd
    • India James
Thank You

For more information about CORE, visit:
www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/default.htm

Flour is not considered a ready-to-eat food!