Understanding Pathogenic *E. coli* in Flour and Other Low Moisture Food Products

Tortilla Industry Association
2016 Technical Conference

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Why are we discussing this?

2009

Toll House cookie dough recalled, linked to E. coli

WASHINGTON (CNN) — Two federal agencies warned consumers Friday not to eat refrigerated cookie dough.

Updated 2:20 p.m. EDT, Fri June 19, 2009

The company said it is 300,000 cases of the dough with reports of food-borne illness.

There are concerns that people can be contaminated with the E. coli strain, which causes vomiting and diarrhea. The administration and the Control and Prevention for the elderly can suffer more.

Nestlé issued a statement saying that a strain implicated in the bean detected in our product was not detected in our product. We are informing our consumers of this voluntary recall and we are working with the regulatory authorities to determine the source of the strain.

E. Coli in Nestlé Toll House Cookie Dough

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Background (Updated July 13, 2009)

2016

E. Coli Outbreak Could Be Linked to General Mills Flour

by Michel Leddy

MAY 31, 2015, 9:13 PM EDT

General Mills expands flour recall over E. coli outbreak

By Debra Goldschmidt and Jan Christensen, CNN

Updated April 14 PM ET Fri July 3, 2015

General Mills expands flour recall over E. coli outbreak
Escherichia coli

- Gram negative, rod shaped bacterium.
- Part of the Enterobacteriaceae family.
  - Other members of the Enterobacteriaceae family include *Salmonella*, *Cronobacter*, *Klebsiella*, *Erwinia*, *Hafnia*, *Proteus*, et al.
- Commonly found in lower intestines of warm blooded mammals.
- Also found in the environment.
- Most strains of *E. coli* are harmless.
- Others can cause illness:
  - Diarrhea
  - Urinary tract infections
  - Respiratory illness
  - Pneumonia
E. coli Pathotypes

- Not all *E. coli* are created equal!
- Can cause different illnesses:
  - **Enteropathogenic (EPEC)** – Profuse watery diarrheal disease; leading cause of infantile diarrhea in developing areas. Produces intimin (coded by *eae* gene).
  - **Enterotoxigenic (ETEC)** – Causative agent of travelers’ diarrhea; watery diarrhea with little or no fever. Produces enterotoxins (LT and ST).
  - **Enteroinvasive (EIEC)** – Resemble *Shigella*; invasive, dysenteric form of diarrhea. Humans are primary reservoir.
  - **Enteroaggregative (EAEC)** – Diarrhea in infants and children. Defining trait is a “stacked brick” pattern of adhesion to intestinal cells. The *E. coli* causing the 2011 outbreak in Germany was an EAEC that produced Shiga toxin.
Enterohemorrhagic *E. coli* (EHEC)

- Primary cause of bloody diarrhea, a.k.a. hemorrhagic colitis (HC).
- Can progress into potentially fatal hemolytic uremic syndrome (HUS).
  - Hemolytic anemia (destruction of red blood cells).
  - Acute kidney failure (uremia).
  - Low platelet count (thrombocytopenia).
- Predominantly affects children.
- EHEC are typified by the production of Shiga toxins (*Stx*).
**Enterohemorrhagic *E. coli* (EHEC)**

- There are many serotypes of *Stx*-producing *E. coli* (STEC), but only those clinically associated with HC are designated as EHEC.

- Not all STEC are EHEC!

- *Stx* are also referred to as Vero toxins, because they are toxic to African Green Monkey kidney cells (also known as Vero cells). May see the term VTEC used. This can be used interchangeably with STEC.

- *Stx* enter the bloodstream and bind to GB3 receptors on kidney cells.

- *Stx1* and *Stx2* are most often implicated in human illness, but several different variants of *Stx* exist.
**E. coli** O157:H7

- The EHEC group contains more than 130 serotypes.
- O157:H7 is a particular serotype of *E. coli*.
  - Somatic (O) Antigen Type 157
  - Flagellar (H) Antigen Type 7
- O157:H7 is the most prototypic EHEC serotype and is the one that is most often implicated in illness worldwide.
- First recognized as a human pathogen in 1982.
- Caused two prominent outbreaks of HC in Oregon and Michigan.
E. coli O157:H7

3 children remain critical from E. coli

Associated Press

SEATTLE — Three children remained in critical condition Tuesday in a bacteria outbreak linked to contaminated and undercooked Jack in the Box hamburgers. They included a Bellingham boy who underwent surgery.

Two-thirds of the colon of Riley DeWitt, 16 months, was removed in an operation last weekend, and he remained in critical condition at Children's Hospital, spokesman Dean Forbes said.

The boy experienced internal bleeding Sunday night and his blood pressure was erratic, said his father, Darin DeWitt.

"There's nothing to suggest there is an alarming number of secondary cases so far," said Dr. John Kobayashi, the state's chief epidemiologist. Also in critical condition at Children's were Sara Brainee Kiger, 11, and treatment of pneumonia, Jane Anne Wilder of the hospital said in a prepared statement.

Cingoranelli developed E. coli enterocolitis after eating a tainted Jack in the Box burger and was admitted to Swedish on Jan. 22, Kobayashi said. The man was discharged five days later after testing negative for the E. coli bacterium.

On Jan. 31 Cingoranelli was evaluated at the hospital's emergency room for pleurisy, a lung ailment, Wilder said.

Pneumonia is not recognized as a complication of E. coli enterocolitis, said Kobayashi and Dr. Brian Goodell, executive director of Swedish.

Six infected children remained in Mary Bridge Children's Hospital in Tacoma. Four were in intensive care in serious condition and two were satisfactory, spokesman Todd Kelley said. The two newest E. coli patients, admitted over the weekend, have secondary infections.

More than 125 people have been hospitalized in the outbreak, and two children have died. One had eaten a Jack in the Box hamburger and the source of the other's infection has not been identified.

A county-by-county tally of E. coli cases Monday included 176 in King;...
**E. coli O157:H7**

- 1993 Jack-In-The-Box outbreak drastically changed the food safety landscape for the beef industry.
- Led USDA to declare *E. coli* O157:H7 as an adulterant for raw ground beef products in 1994; in 1999 all non-intact raw beef.
- Led USDA to institute the “Mega Reg” in 1996:
  - Mandatory HACCP
  - Mandatory SSOPs
  - Mandatory Generic *E. coli* Performance Criteria
  - Mandatory *Salmonella* Performance Criteria
E. coli O157:H7

- Cattle are a primary reservoir.
- Also carried by sheep and humans.
- Associated foods include:
  - Undercooked Raw Ground Beef
  - Alfalfa Sprouts/Leafy Greens
  - Unpasteurized Fruit Juices
  - Dry-Cured Salmai
  - Cheese Curds

Sickness from apple juice spreads in US

The Virulent E. Coli Found in Salami

E. COLI, the bacteria found mostly in hamburger, which killed four children in 1983 and have made thousands of others ill, sickened 23 people in California and Washington State last month. This time, though, the bacteria were found in salami, a product that had never before been connected with an outbreak.
Non-O157 “Big Six” STEC

- 2005 paper published by the CDC indicated that 71% of EHEC diseases that were not caused by *E. coli* O157:H7 were primarily due to six other O serogroups (O26, O111, O103, O121, O45, and O145).

- Colloquially became known as the “Big Six STEC.”

- In Europe there are only four that are part of this group (O26, O103, O111 and O145).
Non-O157 “Big Six” STEC

In 2011 USDA declared the “Big Six” STEC as adulterants in raw non-intact beef products in addition to O157:H7.

Rules and Regulations

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service
9 CFR Parts 416, 417, and 430
[Docket No. FSIS–2010–0023]
Shiga Toxin-Producing Escherichia coli in Certain Raw Beef Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Response to comments on final determination; planned implementation for testing raw beef manufacturing trimmings.

raw beef products tested by FSIS for E. coli O157:H7, including ground beef.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Background:

On September 20, 2011, FSIS published a document in the Federal Register announcing its determination that raw, non-intact beef products, or raw, intact beef products that are intended for use in raw non-intact product, that are contaminated with Shiga toxin-producing Escherichia coli (STEC) O26, O45, O103, O111, O121, and O145 are adulterated within the meaning of 21 U.S.C. 601(m)(1) [76 FR 58187; Sept. 20, 2011].

The products are adulterated because they contain a poisonous or deleterious substance that may render them injurious to health. FSIS stated that raw, non-intact beef products that are contaminated with these STEC are therefore adulterated.
FDA Stance on Pathogenic *E. coli*

- Not as clear cut as USDA as to which are adulterants.
- More on a case-by-case basis.
- FDA uses language from FFDCA, 21 U.S. Code § 342, to identify adulterated foods:

  “A food shall be deemed to be adulterated — If it bears or contains a poisonous or deleterious substance which may render it injurious to health…”
2009 Cookie Dough Outbreak

- Multistate outbreak of *E. coli* O157:H7 linked to eating raw, refrigerated, prepackaged cookie dough.
- 72 persons from 30 states were infected with a particular strain of *E. coli* O157:H7; 34 hospitalizations, 10 instances of HUS, no deaths.
- Illnesses linked to consumption of raw Nestle Toll House cookie dough.
- *E. coli* isolated from recalled products by FDA.
- “*E. coli* O157:H7 has not been previously associated with eating raw cookie dough.” nor any flour-based products for that matter...
- Later determined that flour being used was the likely culprit.
2009 Cookie Dough Outbreak

- At 2011 International Association for Food Protection Annual Meeting Nestle presented data that it had collected in wake of the outbreak.
- Flour was only ingredient not cleared at the supplier level, so focused on testing flour to see if the pathogen could be found.
- Five laboratories put to work to find *E. coli* O157:H7 in flour.
- Tested 30 samples from each of 1,074 lots for a total of 32,220 batches.
- Found one positive sample for an incidence rate of 0.003.
- No comparable work had been done until Nestle took on this project.
- Still lacking substantial data on the prevalence of *E. coli* in flour.
2016 Flour Outbreak

- Multistate outbreak of STEC infections linked to flour.
- Two different outbreak strains identified: *E. coli* O121 and *E. coli* O26
- 63 people infected from 24 states; 17 hospitalizations, 1 instance of HUS, no deaths reported.
- Epidemiological, laboratory, and traceback evidence indicated that flour produced at a General Mills facility in Kansas City, MO was the likely source of the outbreak.
2016 Flour Outbreak

- Timeline of Events:
  - May 31, 2016 – Initial flour recall of 10 million pounds
  - July 1, 2016 – Expanded flour recall
  - July 11, 2016 – Two flavors of Betty Crocker Cake Mix recalled
  - July 25, 2016 – Expanded retail flour recall to total of 45 million pounds
Other outbreaks in low moisture foods…

- 1994 – Dry-cured salami – 23 cases in Washington and Northern California; 3 hospitalizations and one case of HUS in a 2-year old boy.
- 1995 – Deer jerky – six confirmed and five presumptive cases in Oregon.
- 2011 – In-shell hazelnuts – eight ill persons from Michigan, Minnesota, and Wisconsin; 50% were hospitalized, no deaths.
- 2011 – Lebanon bologna - 14 ill persons from Maryland, New Jersey, North Carolina, Ohio, and Pennsylvania; 23% hospitalized, no deaths.
How does *E. coli* get into flour?

- Unfortunately not much published research is available.
- 1993 survey demonstrated that 12.8% of U.S. wheat flour contained *E. coli* (nonpathogenic strains) and 1.3% contained *Salmonella*.
- 2015 paper from Martinez, et al.
How does *E. coli* get into flour?

- We don’t know...
- Research on transmission routes for *E. coli* in produce suggests that common contamination sources are soil, seed, and irrigation water.
- *E. coli* O157:H7 can survive in soil for 2 months in plain soil, 6 months when temperatures are around 4°C, and up to 500 days in frozen soil.
- Water sources can also become contaminated with *E. coli* O157:H7 through run-off from livestock operations during the rainy season.
- Survival of *E. coli* O157:H7 on seeds can be as long as one year and can be recovered in high numbers when plants start to sprout again.
- Also has been shown that *E. coli* O157:H7 can use roots to translocate internally into plants, especially in the intercellular space.
- Also have seen colonization of radish hypocotyls and cotyledons and stomata of leaves. Have also seen movement of *E. coli* O157:H7 within the *Arabidopsis thaliana* plant whereby it reaches flowers and seeds.
Martinez, et al. 2015

- Inoculated wheat seeds and planted in sterile soil to determine whether internalized *E. coli* O157:H7 could be recovered from seedlings. Found that 2 out of 96 seedlings contained internalized *E. coli* O157:H7.

- Also planted sterile wheat seeds into inoculated soil. Found that 5 out of 100 seedlings contained internalized *E. coli* O157:H7.

- Planted sterile seeds in sterile soil and used inoculated irrigation water. Found that 5 out of 50 seedlings contained internalized *E. coli* O157:H7.
Martinez, et al. 2015

- Sprayed heads of wheat at the flowering growth stage with water contaminated with *E. coli* O157:H7.
- Demonstrated that *E. coli* populations increased substantially on wheat flower heads after 24 h.
- Also demonstrated that *E. coli* could survive on the wheat heads for up to 15 d after inoculation onto the heads.
- Most important finding of the study was that irrigation of wheat plants at the flowering growth stage is the most likely route of contamination under real environmental conditions, since *E. coli* O157:H7 showed a high rate of survival on the wheat heads.
What can the baking industry do?

- Source wheat from farming operations that utilize good agricultural practices. Audit the farming operations to ensure compliance.

- Ensure that milling operations do not exacerbate any microbiological issues. Tempering and other processes at the mill may provide moisture and ideal temperature for microbiological growth.

- If these processes are part of the milling process, ensure that the milling operation is using some sort of intervention (e.g. chlorination of tempering water) to help control microbiological outgrowth.

- For high-risk products (i.e. products that may be consumed raw or those that may come into contact with flour after being subjected to a kill step) consider using heat-treated flour ($$$).

- Validate that the kill steps that are being used to provide pathogen lethality in the baking process are actually achieving the intended reductions for that particular product.
What can the baking industry do?

− Validations of kill steps:
  − Laboratory-based study – inoculate pathogens into products and subject them to the time and temperature conditions achieved at the plant.
  − In-plant surrogate study – use surrogate organisms for pathogens, inoculate products at the plant, and use the actual equipment at the plant to provide the processing for the samples.
    − Channaiah, et al. 2016: Validation of Baking To Control Salmonella Serovars in Hamburger Bun Manufacturing, and Evaluation of Enterococcus faecium ATCC 8459 and Saccharomyces cerevisiae as Nonpathogenic Surrogate Indicators
  − Modeling study – collect temperature and time data with a data logger and place into a model to determine the degree of lethality.
What can the baking industry do?

- Overall, understand that pathogenic *E. coli* are a hazard that should be properly addressed in your food safety plan that is developed in accordance with the regulations pertaining to FSMA.

- Validation is a critical component of FSMA, so ensure that your processes are properly validated to control pathogenic *E. coli*. 
E. coli HAPPENS!
SO BE PREPARED...
THANK YOU!

QUESTIONS??