

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

Tortilla Industry Association
2016 Technical Conference

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Food Safety Net Services, Ltd.



Why are we discussing this?

2009

Toll House cookie dough recalled, linked to E. coli

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

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



Consumers are advised to throw out all prepackaged, refrigerated Nestlé Toll House cookie dough products.

The company said it is reporting 300,000 cases of the do reports of food-borne ill

There are concerns that be contaminated with the 0157:H7, which causes vomiting and diarrhea, the Administration and the Control and Prevention the elderly can suffer mc

Nestlé issued a state me coli strain implicated in been detected in our pr of our consumers is par initiating this voluntary r

1/nestle-cookie-dough-warning/index.html?ref=nextin#cnSTCText

E. Coli in Nestlé Toll House Cookie Dough

Topics on this page

- Background
- News
- Resources for Consumers
- Resources for Industry

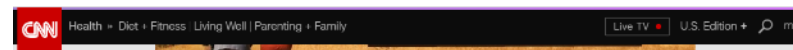


Background (Updated July 13, 2009)

2016

E. Coli Outbreak Could Be Linked to General Mills Flour

by Michal Addady @michal_addady MAY 31, 2016, 5:13 PM EDT



General Mills expands flour recall over E. coli outbreak

By Debra Goldschmidt and Jen Christensen, CNN
Updated 4:49 PM ET, Fri July 1, 2016

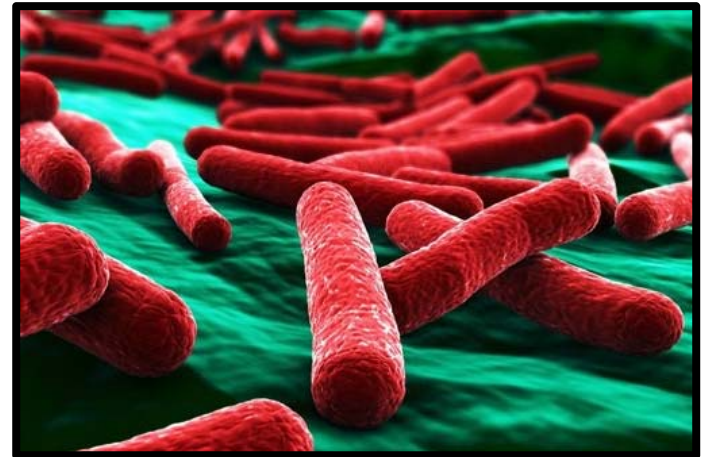
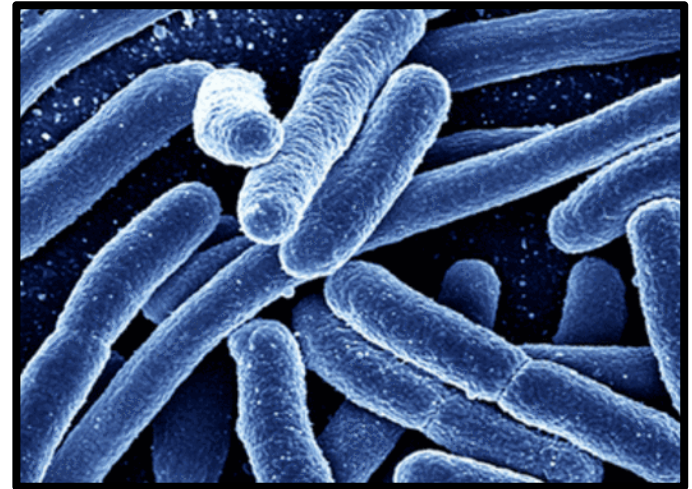


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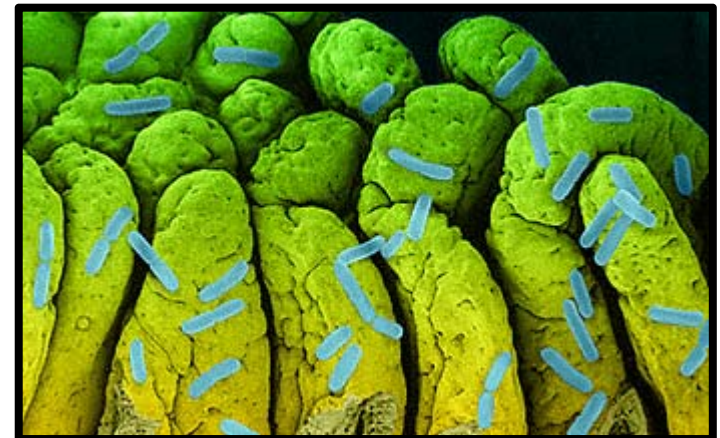
Escherichia coli

- 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



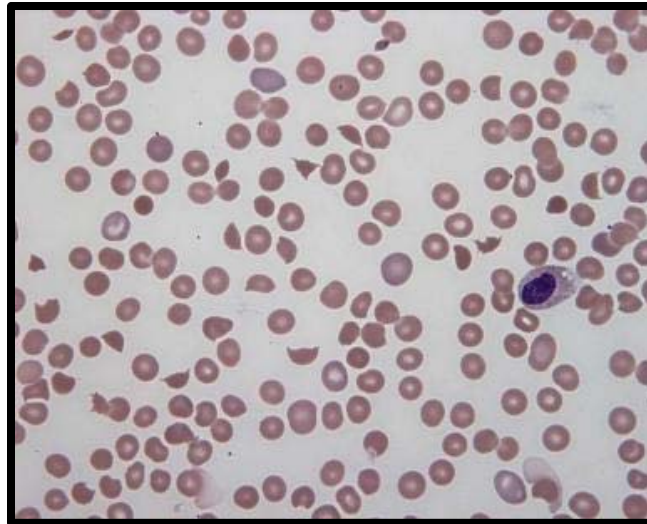
E. coli Pathotypes

- 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.
 - Enteraggregative (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.



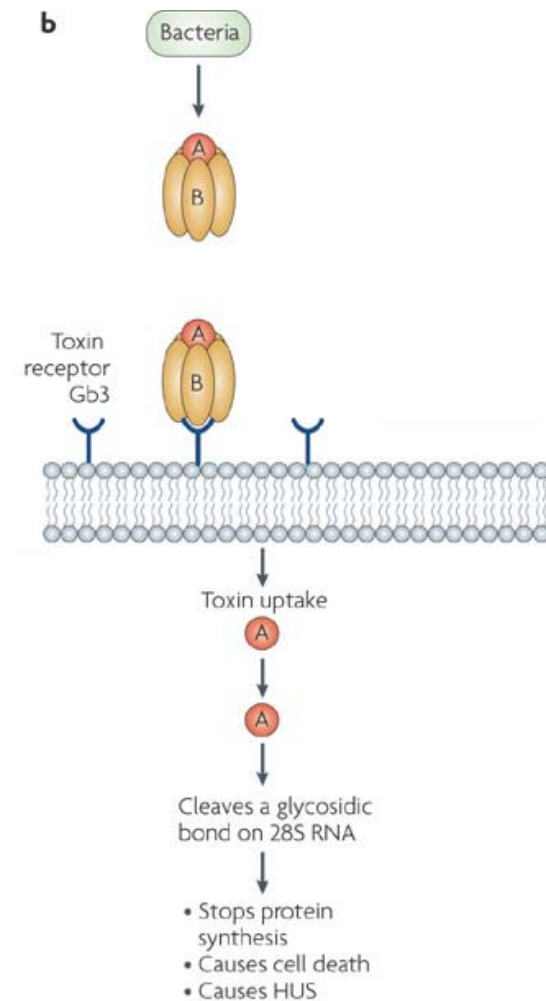
Enterohemorrhagic *E. coli* (EHEC)

- 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.

SPARTANBURG HERALD-JOURNAL, SPARTANBURG, S.C., THURSDAY, MARCH 24, 1983—Page A7

New-Found Fast Food Illness Is Traced To Rare Bacteria

BOSTON (AP)—A mysterious intestinal ailment that first struck diners at a fast-food chain is a new-found disease caused by a rare bacteria, and it has spread across the United States, researchers say.

Federal disease experts are seeking the source of the organism so they can wipe it out, but they fear it is becoming established in the nation's food system.

The first major outbreak appeared last year among 47 people who ate at McDonald's restaurants in Michigan and Oregon. It has since occurred among patients at a Canadian hospital, and 48 scattered cases have been reported in the United States.

The disease is hemorrhagic colitis, and it is caused by a rare form of the common bacteria *E. coli*. Victims have severe cramps and bloody diarrhea, and the sickness lasts from three days to more than a week.

Doctors from the Centers for Disease Control in Atlanta call the ailment "a clinically distinctive gastrointestinal illness" and say it is apparently transmitted by undercooked meat.

Although the disease occurred at least once before, doctors did not recognize it as unique until after the restaurant-chain outbreak.

A report on their inquiry into the disease, directed by Dr. Lee W. Riley, was published in Thursday's *New England Journal of Medicine*.

"If it is a new organism, it may be producing diarrhea by some new, unrecognized mechanism," Riley said in an interview.

The first outbreak was in Medford, Ore., in February and March last year and affected 26 people who had eaten at two McDonald's. Three months later, the disease struck 21 people who were customers at two of the chain's restaurants in Traverse City, Mich.

The victims fell ill about four days after eating the hamburgers, and more than two-thirds of them were hospitalized.

From the patients' stool samples, doctors isolated a very rare form of bacteria called *E. coli* O157:H7. Then they found the same bacteria in a frozen hamburger patty stored at a processing plant. The meat had been kept from a batch that was shipped to the Michigan restaurants.


Steve Leroy, a McDonald's spokesman, declined to comment on the federal report.

In the Michigan outbreak, most victims said they had eaten Big Macs, which have twice as much meat as regular hamburgers.


The illness usually begins with severe cramps, followed by diarrhea. In one typical case, the doctors wrote, "the patient initially noted small amounts of blood, but later the same day the diarrhea became grossly bloody, with bright-red blood, described as 'red blood and no stool.'" About half of the victims also have nausea or vomiting, but fever is rare.

**Children Need
Chiropractic Care!**

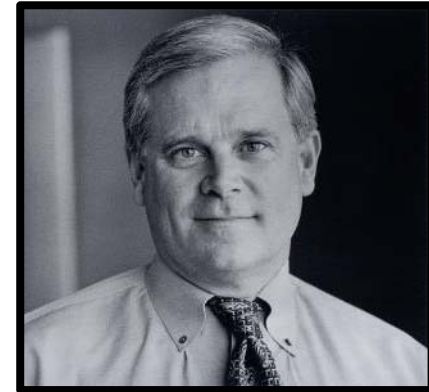
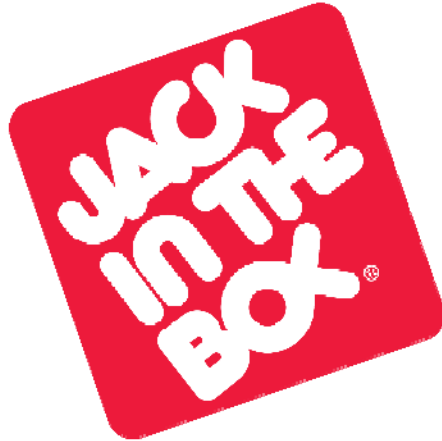
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E. coli O157:H7



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 Detwiler, 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 Detwiler.

“There’s nothing to suggest there is an alarming number of secondary cases so far.”

DR. JOHN KOBAYASHI,
state epidemiologist

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 Brienne Kiner, 10,

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.

fections.

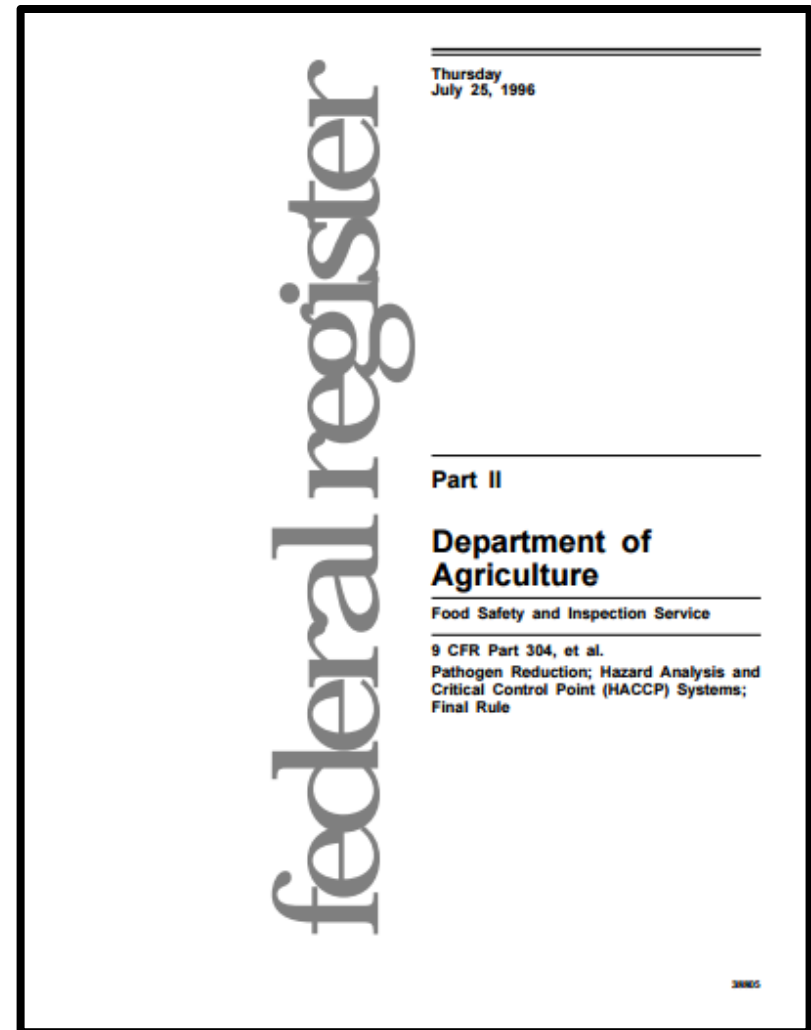
Six infected children remained in Mary Bridge Children’s Hospital in Tacoma. Four were in intensive care in serious condition and two were satisfactory, spokesman Todd Kelley said. The two newest *E. coli* patients, admitted over the weekend, have secondary infections.

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;

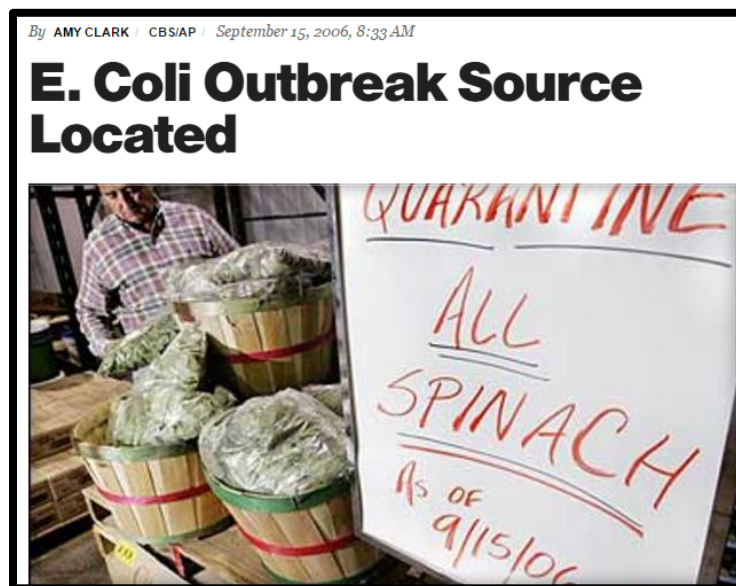
E. coli O157:H7

- 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 Salami
 - Cheese Curds



Sickness from apple juice spreads in US

SAM PERRY
Reuters

HALF MOON BAY, California – An outbreak of bacterial poisoning linked to apple juice spread beyond Washington state on Thursday when officials in Colorado and California reported new suspected cases.

At least 13 children and young adults in the Seattle area have been stricken since last week by a potentially fatal strain of the E coli bacteria, including at least 10 who became sick after drinking Odwalla apple juice.

Colorado state health officials said another four cases of E coli sickness probably were linked to Odwalla juice products, and four more were being investigated.

In California, parents of a 2-year-old girl hospitalized in critical condition said she had drunk the company's juice.

At Odwalla Inc headquarters in this seaside town, grim-faced company officials said they were expanding a recall of apple juice-based products to cover several varieties of vegetable juices made on the same production line at its Dinuba, California, plant.

"Right now our deepest concern is for the health and safety of our customers and for anyone in the public," Greg Stetschinski, chairman and co-founder of the 16-year-old company, said at a news conference in the company parking lot.

"To be focused on health and nutrition all of your life and have this incident happen – we're deeply affected by it," he said.

The company's stock plunged \$6.25 (Bt155) to \$12.125 a share in Nasdaq trading, but executives said they were not focused on the financial impact of the outbreak.

US Food and Drug Administration officials said they had collected samples of Odwalla products for analysis from throughout the company's distribution region, which includes seven Western states and British Columbia.

The company routinely saves juice from each production run, and was able to provide samples from batches that may have been consumed last week, when the first cases cropped up, said FDA spokesman Arthur Whitmore.

He said DNA testing on the samples would begin on Thursday or on Friday and continue through the weekend to determine whether they contain the strain of E coli that caused the outbreak.

In the Seattle area several children have undergone kidney dialysis and one remained hospitalized due to complications from the virulent E coli O157:H7 bacteria.

The microbe normally lives in cattle but can be transmitted to humans through manure or improper slaughtering and can cause brain damage or death, especially in young children.

The New York Times

Home & Garden

WORLD U.S. N.Y. / REGION BUSINESS TECHNOLOGY SCIENCE HEALTH

FASHION & STYLE DINING & WINE HOME & GARDEN WEDDINGS/CELEBRATIONS

The Virulent E. Coli Found in Salami

By MARIAN BURROS
Published: January 25, 1995

E. COLI, the bacteria found mostly in hamburger, which killed four children in 1993 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).

Non-O157 Shiga Toxin–Producing *Escherichia coli* Infections in the United States, 1983–2002

John T. Brooks,^{1*} Evangeline G. Sowers,¹ Joy G. Wells,¹ Katherine D. Greene,¹ Patricia M. Griffin,¹ Robert M. Hoekstra,² and Nancy A. Strockbine¹

¹Foodborne and Diarrheal Diseases Branch and ²Biostatistics and Information Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia

- 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.

31975

Rules and Regulations

Federal Register
Vol. 77, No. 105
Thursday, May 31, 2012

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: Rachel Edelstein, Acting Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, (202) 205-0495.

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 58157; Sep. 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 also unhealthful and

outreach and information that would be most useful to establishments preparing for implementation by the Agency of its sampling and verification testing program, and information that foreign governments might need to address inspection equivalency or implementation concerns.

FSIS extended the public comment period from November 21, 2011, to December 21, 2011, and held a public meeting by teleconference on December 1, 2011. (76 FR 72331; Nov. 23, 2011).

In response to comments received from industry, FSIS issued a **Federal Register** notice (77 FR 9888; Feb. 21, 2012) in which FSIS moved the implementation date to June 4, 2012, for routine verification activities, including testing, for the six specified STEC in raw beef manufacturing trimmings derived from cattle slaughtered on or after June 4, 2012. To allow establishments time to implement appropriate changes in their food safety systems, including changes in process control procedures, FSIS will generally not treat as adulterated raw beef products found to have these pathogens

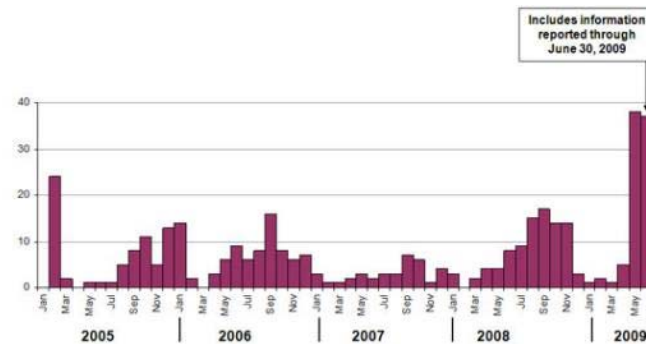
FDA Stance on Pathogenic *E. coli*

- 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.



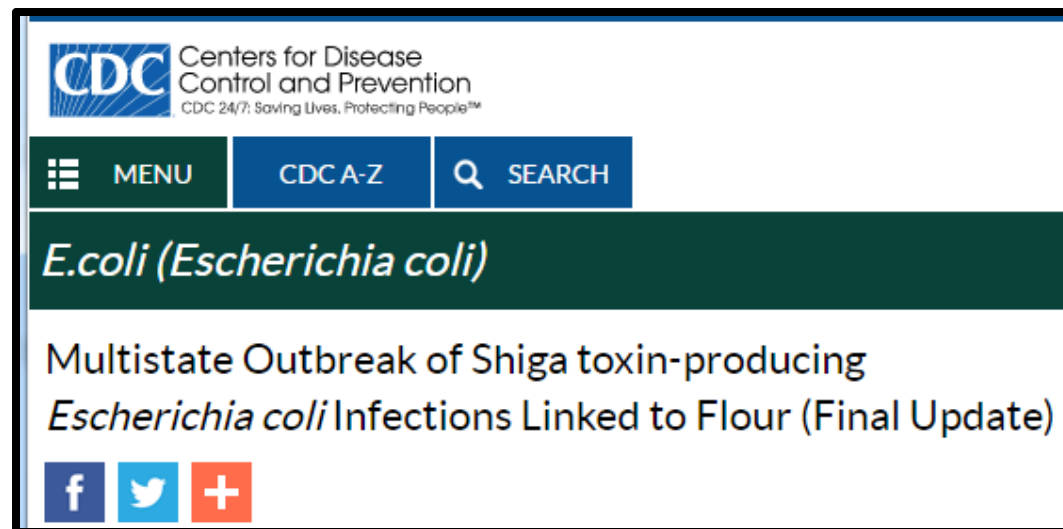
2009 Cookie Dough Outbreak



- 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.



The screenshot shows the top portion of a CDC webpage. At the top left is the CDC logo with the text "Centers for Disease Control and Prevention" and the tagline "CDC 24/7: Saving Lives. Protecting People™". Below the logo is a navigation bar with three buttons: "MENU", "CDC A-Z", and "SEARCH". The main content area features a dark green header with the text "*E.coli (Escherichia coli)*". Below this is the title of the page: "Multistate Outbreak of Shiga toxin-producing *Escherichia coli* Infections Linked to Flour (Final Update)". At the bottom of the content area are three social media icons: Facebook, Twitter, and a plus sign for additional sharing options.

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.

Journal of Food Protection, Vol. 78, No. 3, 2015, Pages 518–524
doi:10.4315/0362-028X.JFP-14-298
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Transmission of *Escherichia coli* O157:H7 to Internal Tissues and Its Survival on Flowering Heads of Wheat

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MS 14-298: Received 23 June 2014/Accepted 28 October 2014

ABSTRACT

Escherichia coli O157:H7 is a human pathogen that can cause bloody diarrhea, hemorrhagic colitis, and hemolytic uremic syndrome. *E. coli* O157:H7 illnesses are mainly associated with undercooked beef; however, in recent years, outbreaks have been linked to fresh produce, such as spinach, lettuce, and sprouts. In 2009, flour was implicated as the contamination source in

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 in to 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.
 - AIB Models are useful for this:
<https://www.aibonline.org/aibOnline/develop-your-product-solutions/baking-process-kill-step-calculators.aspx>

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*.

VALIDATED



E. coli
HAPPENS!

SO BE PREPARED...

THANK YOU!

QUESTIONS??