

FDA Investigated Multistate Outbreak of *E. coli* O157:H7 Infections Linked to SoyNut Butter

May 4, 2017

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Fast Facts

- The U.S. Food and Drug Administration (FDA), along with the Centers for Disease Control and Prevention (CDC) and state and local authorities, investigated a multistate outbreak of Shiga toxin-producing *Escherichia coli* (*E. coli*) O157:H7 infections linked to SoyNut Butter products manufactured by Dixie Dew Products, Inc. (Dixie Dew) of Erlanger, Ky., and distributed by The SoyNut Butter Company of Glenview, Ill.
- Thirty-two illnesses were reported from Arizona, California, Florida, Illinois, Massachusetts, Maryland, Missouri, New Jersey, Oregon, Virginia, Washington and Wisconsin.
- The SoyNut Butter Company recalled all lots and flavors of I.M. Healthy SoyNut Butter, I.M. Healthy Granola, and Dixie Diner's Club brand Carb Not Beanit Butter. Another company, Pro Sports Club, recalled 20/20 Life Styles Yogurt Peanut Crunch bars because they were made with SoyNut Butter supplied by The SoyNut Butter Company.
- On March 28, 2017, the FDA suspended the Food Facility Registration for Dixie Dew, the contract manufacturer for The SoyNut Butter Company's SoyNut Butter products after an inspection of the facility identified insanitary conditions that could lead to products becoming contaminated with *E. coli* O157:H7 in Dixie Dew's finished products. As of May 4, 2017, Dixie Dew's registration remains suspended.
- On Thursday, May 4, 2017, the **(CDC) (<https://www.cdc.gov/ecoli/2017/O157H7-03-17/index.html>)** announced that the outbreak investigation is over. Although the investigation is over,

illnesses may still occur if people eat the recalled products and get sick. A list of the recalled products and how to identify them can be found here: **[The Soynut Butter Co Expands Recall to All I.M. Healthy Soynut Butters And I.M. Healthy Granola Because of Possible Health Risk \(https://www.fda.gov/Safety/Recalls/ucm545368.htm\)](https://www.fda.gov/Safety/Recalls/ucm545368.htm)**

What is the Problem and What is Being Done About It?

The FDA and the CDC, along with state and local health officials, investigated an outbreak of Shiga toxin-producing *E. coli* O157:H7 infections linked to the consumption of I.M. Healthy brand SoyNut Butter produced by The SoyNut Butter Company of Glenview, Ill., and manufactured by Dixie Dew Products, Inc. of Erlanger, Ky.

[According to the CDC \(https://www.cdc.gov/ecoli/2017/o157h7-03-17/index.html\)](https://www.cdc.gov/ecoli/2017/o157h7-03-17/index.html), as of May 4, 2017, a total of 32 people infected with the outbreak strain of *E. coli* O157:H7 were reported from 12 states. The number of ill people identified in each state was as follows: Arizona (4), California (5), Florida (2), Illinois (1), Maryland (1), Massachusetts (1), Missouri (1), New Jersey (1), Oregon (11), Virginia (2), Washington (2), and Wisconsin (1). Twelve ill people were hospitalized, and nine people developed hemolytic uremic syndrome (HUS), a potentially life-threatening type of kidney failure. Twenty-six of the 32 illnesses were reported in children under the age of 18. No deaths were reported. Illnesses started on dates ranging from January 4, 2017 to April 18, 2017. Ill people ranged in age from 1 to 70 years, with a median age of 9.

The epidemiologic, laboratory, and traceback evidence indicated that I.M. Healthy SoyNut Butter was the likely source of the outbreak. In interviews conducted by state and local health department officials, ill people or their family members answered questions about the foods they ate and other exposures in the week before they became ill. Twenty-five of the 32 people reached for interview reported either eating I.M. Healthy SoyNut Butter at home in the week before they became ill, attending a facility that served I.M. Healthy SoyNut Butter, or attending childcare centers that served I.M. Healthy SoyNut Butter and the I.M. Healthy granola.

On March 2, 2017, the FDA and CDC held a call with the owners of The SoyNut Butter Company to advise the firm about the multistate outbreak linked to its SoyNut Butters.

On March 3, 2017, The SoyNut Butter Company voluntarily recalled its I.M. Healthy Original Creamy SoyNut Butter with Best By dates of August 30, 2018 and August 31, 2018. On March 4, 2017, The SoyNut Butter Company expanded the recall of its I.M. Healthy Original Creamy SoyNut Butter to include product packaged in 15oz. plastic jars with Best By dates of July 05, 2018, August 30, 2018, and August 31, 2018; individual portion cups with a Best By date of August 08, 2018; and 4lb. plastic tubs with Best By dates of November 16, 2018 and July 25, 2018.


On March 7, 2017, The SoyNut Butter Company recalled all lots of I.M. Healthy SoyNut Butter and I.M. Healthy Granola. I.M. Healthy SoyNut Butter is packaged in 15 oz. plastic jars, individual portion cups, 4 lb. plastic tubs or 45 lb. pails. The products are available in Original Creamy, Chunky, Honey Creamy, Unsweetened and Chocolate. I.M. Healthy Granola is packaged in individual serving packages, 12 oz. bags, 50 oz. bags, and 25 lb. bulk bag. I.M. Healthy Granola is available in Original, Apple, Blueberry, with Raisin, and Cranberry.

On March 10, 2017, The SoyNut Butter Company expanded its recall to include all best buy dates of Dixie Diner's Club brand Carb Not Beanit Butter. The recalled product was only available for purchase via mail order or online portals.

On March 24, 2017, Pro Sports Club recalled 20/20 Life Styles Yogurt Peanut Crunch bars because they were made with soy nut butter supplied by The SoyNut Butter Company.

Consumers should not eat, and childcare centers and other institutions should not serve, any variety of I.M. Healthy brand SoyNut Butter, I.M. Healthy brand granola, or Dixie Diner's Club brand Carb Not Beanit Butter products. The SoyNut Butter Company's SoyNut Butters have a long shelf life, and jars of the products may be kept in peoples' homes for a long time. The FDA and CDC urge consumers to check their pantry thoroughly, and if any products are found to throw them away. Consumers unaware of the recall could continue to eat these recalled products and potentially get sick. Consumers should not eat recalled 20/20 Lifestyle Yogurt Peanut Crunch Bars.

What are the Symptoms of *E. coli* O157:H7 Infection?

The symptoms of Shiga toxin-producing *E. coli* (STEC) infections vary for each person but often include severe stomach cramps and bloody diarrhea. If there is fever, it is usually not very high (less than 101 degrees **Fahrenheit** (<https://en.wikipedia.org/wiki/Fahrenheit>)  (<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)/less than 38.5 degrees Celsius). Most people get better within 5–7 days. Some infections are very mild, but others are severe or even life-threatening.

Around 5–10 percent of those who are diagnosed with STEC infection develop a potentially life-threatening complication, known as hemolytic uremic syndrome (HUS).

Symptoms of HUS include fever, abdominal pain, feeling very tired, decreased frequency of urination, small unexplained bruises or bleeding, and pallor. Most people with HUS recover within a few weeks, but some suffer permanent damage or die. People who experience these symptoms should seek emergency medical care immediately. Persons with HUS should be hospitalized because their kidneys may stop working (acute renal failure), but they may also develop other serious problems such as hypertension, chronic kidney disease, and neurologic problems.

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Who is at Risk?

People of any age can become infected. Children under the age of 5 years, adults older than 65, and people with weakened immune systems are more likely than others to develop severe illness, including HUS, but even healthy older children and young adults can become seriously ill.

What Specific Products were Recalled?

- Dixie Diner's Club brand Carb Not Beanit Butter (only available online and through mail order)
- All flavors and sizes of I.M. Healthy SoyNut Butters
- All flavors and sizes of I.M. Healthy Granola
- Pro Sports Club 20/20 Life Styles Yogurt Peanut Crunch Bars

What Do Consumers Need To Do?

The FDA urges consumers not to eat any of the recalled products and to check their homes carefully for any of The SoyNut Butter Company's products. Do not eat or serve I.M. Healthy SoyNut Butter or I.M. Healthy Granola, Dixie Diner's Club brand Carb Not Beanit Butter, or Pro

Sports Club 20/20 Life Styles Yogurt Peanut Crunch Bars. Even if some SoyNut Butter or granola was eaten or served and no one got sick, throw the rest of the product away. Put it in a sealed bag in the trash so that children, pets, or other animals cannot eat it.

Contact your health care provider if you think you or your child became ill after eating any of the recalled products, especially if you or your child develop diarrhea that lasts for more than three days, or is accompanied by high fever, blood in the stool, or so much vomiting that you cannot keep liquids down and you pass very little urine.

What Do Retailers Need To Do?

The SoyNut Butter Company recalled all of its I.M. Healthy SoyNut Butter, I.M. Healthy Granola products, and Dixie Diner's Club brand Carb Not Beanit Butter. Retailers should remove all I.M. Healthy SoyNut Butter and I.M. Healthy Granola products from sale and should not manufacture any products using the recalled products. For questions or concerns, please call the company at 800-288-1012.

Pro Sports Club has also recalled 20/20 Life Styles Yogurt Peanut Crunch Bars because they were made with SoyNut Butter from The SoyNut Butter Company. For questions or concerns, please call the company at 1-425-895-6533.

Who should be Contacted?

The FDA encourages consumers with questions about food safety to call 1-888-SAFEFOOD, Monday through Friday between 10 a.m. and 4 p.m. Eastern Time, or consult the **FDA website** (<https://www.fda.gov/default.htm>).

Additional Information

- CDC: **Multistate Outbreak of Shiga toxin-producing Escherichia coli O157:H7 Infections Linked to I.M. Healthy Brand SoyNut Butter** (<https://www.cdc.gov/ecoli/2017/o157h7-03-17/index.html>)
- **FDA Suspends Food Facility Registration of Dixie Dew Products, Inc.** ([/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm549734.htm](https://www.fda.gov/food/ recalls-outbreaks-emergencies-safety-alerts-advisories/ucm549734.htm))
- **The Soynut Butter Co Expands Recall to all I.M. Healthy Soynut Butters and I.M. Healthy Granola Because of Possible Health Risk** ([/Safety/Recalls/ucm545368.htm](https://www.fda.gov/safety/recalls/ucm545368.htm))
- **The Soynut Butter Co Expands Recall to Include Dixie U.S.A Products Because of Possible Health Risk** ([/Safety/Recalls/ucm546130.htm](https://www.fda.gov/safety/recalls/ucm546130.htm))
- **Pro Sports Club Recalls Yogurt Peanut Crunch Bar Because of Possible Health Risk** ([/Safety/Recalls/ucm548563.htm](https://www.fda.gov/safety/recalls/ucm548563.htm))
- Foodsafety.gov: **Food Poisoning - E. coli** (<https://www.foodsafety.gov/poisoning/causes/bacteriaviruses/ecoli/>)
- CDC: **CDC E. coli homepage** (<https://www.cdc.gov/ecoli/>)

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Resources for You

- [FDA Suspends Food Facility Registration of Dixie Dew Products, Inc. \(/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm549734.htm\)](#)

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