Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

The Soynut Butter Co Recalls I.M. Healthy Original Creamy Soynut Butter Because Of Possible Health Risk

For Immediate Release

March 4, 2017

Contact

Consumers

**** 1-800-288-1012

Media

SoyNut Butter Co. \$\square\$ 1-800-288-1012

Announcement

View Product Photos

The SoyNut Butter Co. of Glenview, IL is recalling I.M. Healthy Original Creamy SoyNut Butter product because it may be contaminated with *Escherichia coli* O157:H7 bacteria E. Coli O157:H7). E. coli O157:H7 causes a diarrheal illness often with bloody stools. I.M. Healthy Original Creamy SoyNut Butter was distributed in multiple states and may have been purchased in stores or through mail order. It was also distributed to childcare centers and schools in multiple states.

The product has been packaged in 15 oz plastic jars with the Best By dates <u>July 05, 2018</u>, <u>August 30, 2018</u>, and <u>August 31, 2018</u>; individual portion cups with the Best By date as August 08, 2018; and 4 lb plastic tubs with Best By dates of November 16, 2018 and July 25, 2018.

Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called Hemolytic Uremic Syndrome (HUS). HUS is most likely to occur in young children and the elderly. The condition can lead to serious kidney failure and even death.

Twelve people infected with the outbreak strain of STEC O157:H7 have been reported from five states to date.

The recall was initiated after ill people or their family members answered questions about the foods they ate and other exposures in the week before they became ill. Nine (100%) of the nine people reached for interview reported either eating I.M. Healthy brand SoyNut Butter at home (five people) in the week before they became ill or attending a childcare center that served I.M. Healthy brand SoyNut Butter.

Consumers who have purchased I.M. Healthy SoyNut Butter are urged not to consume the product and return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-288-1012, Monday-Friday 9:00-5:00 CST.

FDA Investigates Multistate Outbreak of E. coli O157:H7 Infections Linked to SoyNut Butter (/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm544964.htm)

###

Follow FDA

- **y** Follow @US FDA (https://twitter.com/US FDA) f

 (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- Follow FDA (https://www.facebook.com/FDA) # (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- Follow @FDArecalls (https://twitter.com/fdarecalls)
 (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- Recent Recalled Product Photos on FDA's Flickr Photostream
 (https://www.flickr.com/photos/fdaphotos/sets/72157663245186459/)
 (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

 Product Photos	e When little en doue,
	. At 100 to 100 and 100 pc
	-
	-







More in Recalls, Market Withdrawals, & Safety Alerts (/Safety/Recalls/default.htm)

Enforcement Reports (/Safety/Recalls/EnforcementReports/default.htm)	
Industry Guidance (/Safety/Recalls/IndustryGuidance/default.htm)	re, ger verer grane med enne
Major Product Recalls (/Safety/Recalls/MajorProductRecalls/default.htm)	~



Multistate Outbreak of Shiga toxin-producing *Escherichia coli* O157:H: Infections Linked to I.M. Healthy Brand SoyNut Butter

'osted March 3, 2017 12:45PM EST

Highlights

- Read the Advice to Consumers and Institutions>>
- CDC, multiple states, and the U.S. Food and Drug Administration (FDA) are investigating a multistate outbreak of Shiga toxin-producing *Escherichia coli* O157:H7 (STEC O157:H7) infections.
 - Twelve people infected with the outbreak strain of STEC O157:H7 have been reported from five states.
 - Six ill people have been hospitalized. Four people developed hemolytic uremic syndrome, a type of kidney failure, and no deaths have been reported.
 - Eleven of the 12 ill people in this outbreak are younger than 18 years old.
- Epidemiologic evidence available at this time indicates that I.M. Healthy brand SoyNut Butter is a likely source of this outbreak. I.M. Healthy brand SoyNut Butter may be contaminated with *E. coli* O157:H7 and could make people sick.
- CDC recommends that consumers do not eat, and childcare centers, schools, and other institutions do not serve, any I.M. Healthy brand SoyNut Butter varieties and sizes, or I.M. Healthy brand granola coated with SoyNut Butter.
 - Even if some of the 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 can't eat it.
- This investigation is ongoing and quickly changing. CDC will provide updates as more information becomes available.

Initial Announcement

March 3, 2017

CDC is collaborating with public health and regulatory officials in several states and the U.S. Food and Drug Administration (FDA) to investigate a multistate outbreak of Shiga toxin-producing *Escherichia coli* O157:H7 (STEC O157:H7) infections.

Public health investigators are using the <u>PulseNet</u> system to identify illnesses that may be part of this outbreak. PulseNet, coordinated by CDC, is the national subtyping network of public health and food regulatory agency laboratories. PulseNet performs DNA fingerprinting on STEC bacteria isolated from ill people by using techniques called <u>pulsed-field gel electrophoresis</u> (PFGE) and <u>whole genome sequencing</u>

(WGS). CDC PulseNet manages a national database of these DNA fingerprints to identify possible outbreaks. In this outbreak, the outbreak strain was defined by PFGE. The DNA fingerprint of the outbreak strain has never been seen before in the PulseNet database.

Twelve people infected with the outbreak strain of STEC O157:H7 have been reported from five states. A list of the states and the number of cases in each can be found on the <u>Case Count Map page</u>.

Illnesses started on dates ranging from January 6, 2017 to February 15, 2017. Ill people range in age from 2 to 48 years, with a median age of 8. Eleven (92%) of the 12 ill people are younger than 18 years old. Among ill people, 58% are male. Six ill people have been hospitalized and four people developed hemolytic uremic syndrome, a type of kidney failure. No deaths have been reported.

This outbreak can be illustrated with a chart showing the number of people who became ill each day. This chart is called an <u>epidemic curve</u> or epi curve. Illnesses that occurred after February 8, 2017 might not yet be reported due to the time it takes between when a person becomes ill and when the illness is reported. This takes an average of 2 to 3 weeks. Please see the <u>Timeline for Reporting Cases of *E. coli* O157:H7 <u>Infection</u> for more details.</u>

Investigation of the Outbreak

Epidemiologic evidence available at this time indicates that I.M. Healthy brand SoyNut Butter is a likely source of this outbreak. SoyNut Butter is a nut-free substitute for peanut butter.

In interviews, ill people or their family members answered questions about the foods they ate and other exposures in the week before they became ill. Nine (100%) of the nine people reached for interview reported either eating I.M. Healthy brand SoyNut Butter at home (five people) in the week before they became ill or attending a childcare center that served I.M. Healthy brand SoyNut Butter or I.M. Healthy brand granola coated with SoyNut Butter (four people). This proportion is significantly higher than expected when compared to the approximately 6% of ill people interviewed during past outbreak investigations who reported eating a ground nut butter or spread other than peanut butter.

I.M. Healthy brand SoyNut Butter may be contaminated with *E. coli* O157:H7 and could make people sick. CDC recommends consumers do not eat any I.M. Healthy brand SoyNut Butter varieties or sizes or I.M. Healthy brand granola coated with SoyNut Butter. Childcare centers, schools, and other institutions should not serve I.M. Healthy brand SoyNut Butter or I.M. Healthy brand granola coated with SoyNut Butter. Multiple varieties and sizes of I.M. Healthy brand SoyNut butter and I.M. Healthy brand granola coated with SoyNut Butter are sold nationwide in stores, online, and to institutions. The products have a shelf life of 2 years.

This investigation is ongoing and quickly changing. CDC will provide updates when more information is available.

At A Glance

• Case Count: 12

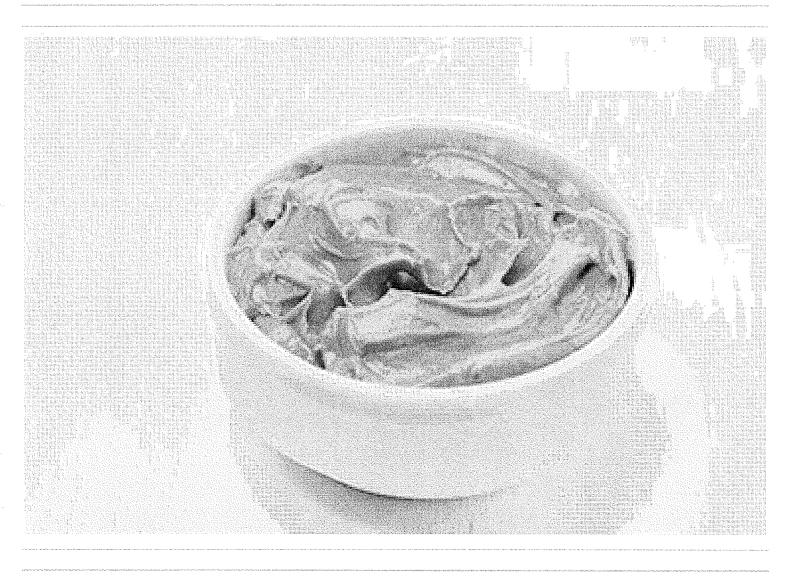
• States: 5

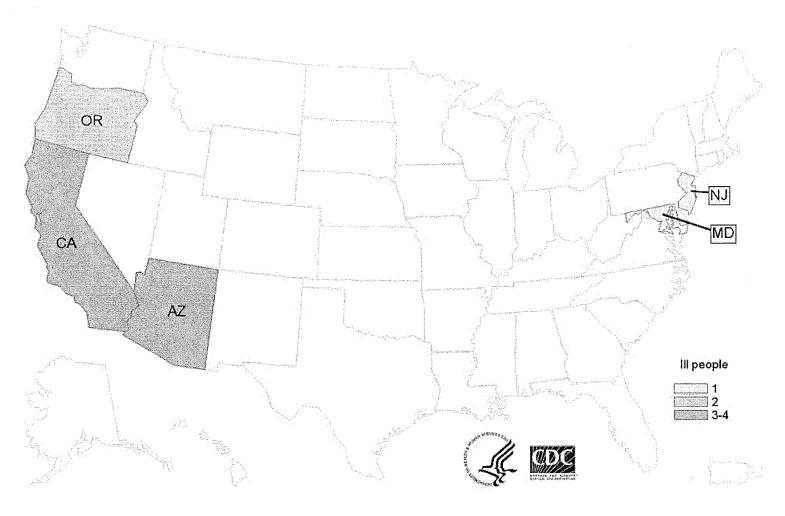
Deaths: 0

• Hospitalizations: 6

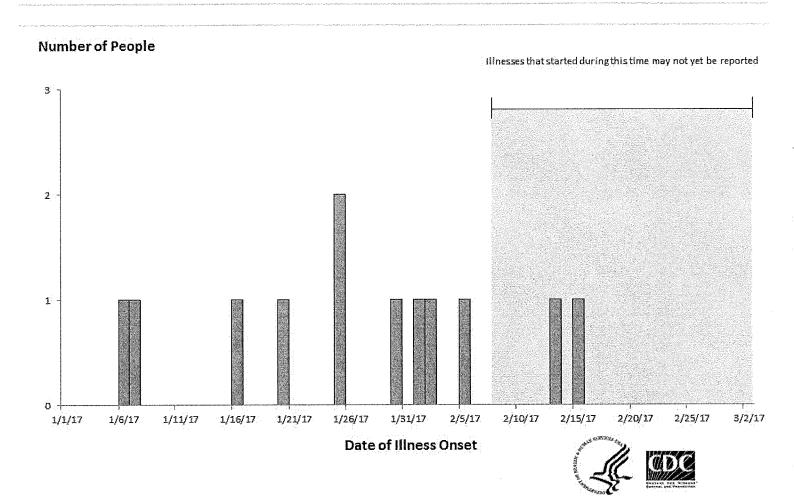
More Information

- Advice to Consumers and Institutions
- Signs & Symptoms
- Key Resources





CLICK TO VIEW CASE COUNT MAPS



age last reviewed: March 3, 2017 age last updated: March 3, 2017

Content source: Centers for Disease Control and Prevention (/)

lational Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (/ncezid/)

Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) (/ncezid/dfwed/index.html)

