



Ohio Department of Agriculture
and
Ohio Department of Health



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To: Health Commissioners, Environmental Health Directors, Nursing Directors, ODA Food Safety Specialists, and Other Interested Parties

Subject: Recall Announcement (ODA/ODH) 2006-50

Date: September 18, 2006

E. coli Outbreak: Recall Expanded
FDA Statement on Foodborne E. coli O157:H7 Outbreak in Spinach

The U.S. Food and Drug Administration (FDA) will continue to provide the public with regular updates on the E. coli O157:H7 outbreak each day until further notice.

Case Reports

To date, 109 cases of illness due to E. coli infection have been reported to the Centers for Disease Control and Prevention (CDC), including 16 cases of Hemolytic Uremic Syndrome (HUS) and one death. Illnesses continue to be reported to CDC. This is considered to be an ongoing investigation.

Symptoms of E. coli O157:H7 Illness

E. coli O157:H7 causes diarrhea, often with bloody stools. Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called HUS. HUS is most likely to occur in young children and the elderly. The condition can lead to serious kidney damage and even death.

States Affected

There are 19 confirmed states: California, Connecticut, Idaho, Indiana, Kentucky, Maine, Michigan, Minnesota, Nevada, New Mexico, New York, Ohio, Oregon, Pennsylvania, Utah, Virginia, Washington, Wisconsin, and Wyoming.

Consumer Advice

FDA advises consumers to not eat fresh spinach or fresh spinach-containing products until further notice. If individuals believe they may have experienced symptoms of illness after consuming fresh spinach or fresh spinach-containing products, FDA recommends that they seek medical advice.

Two (2) Recalls

FDA has been informed that River Ranch, of California, is recalling packages of spring mix containing spinach. River Ranch obtained bulk spring mix containing spinach from Natural Selections. The following brands are involved: Farmers Market, Hy Vee, Fresh and Easy. Products that do not contain spinach are not part of this recall.

Natural Selection Foods, LLC, of San Juan Bautista, California, is recalling all of its products containing spinach in all brands they pack with "Best if Used by Dates" of August 17, 2006 through October 1, 2006. These products include spinach and any salad with spinach in a blend, both retail and food service products. Products that do not contain spinach are not part of this recall.

Natural Selection Foods, LLC brands include: Natural Selection Foods, Pride of San Juan, Earthbound Farm, Bellissima, Dole, Rave Spinach, Emeril, Sysco, O Organic, Fresh Point, River Ranch, Superior, Nature's Basket, Pro-Mark, Compliments, Trader Joe's, Ready Pac, Jansal Valley, Cheney Brothers, Coastline, D'Arrigo Brothers, Green Harvest, Mann, Mills Family Farm, Premium Fresh, Snoboy, The Farmer's Market, Tanimura & Antle, President's Choice, Cross Valley, and Riverside Farms.

The affected products were also distributed to Canada and Mexico. FDA continues to investigate whether other companies and brands are involved.

Lettuce Safety Initiative

The FDA developed the Lettuce Safety Initiative <http://www.cfsan.fda.gov/~dms/lettsafe.html> in response to recurring outbreaks of E.coli O157:H7 in lettuce. As a result of this outbreak, the initiative has been expanded to cover spinach. The primary goals of the initiative are to reduce public health risks by focusing on the product, agents and areas of greatest concern and to alert consumers early and respond rapidly in the event of an outbreak. This initiative is based on the 2004 Produce Safety Action Plan, intended to minimize the incidence of food borne illness associated with the consumption of fresh produce.

FDA continues to work closely with the CDC and state and local agencies to determine the cause and scope of the E.coli outbreak in spinach. Please check www.fda.gov for updates.

The following are questions and answers from FDA regarding E. coli O157:H7.

- **What is E. coli O157:H7**

The E. coli O157:H7 is a bacterium that causes diarrhea that is often bloody; the diarrhea can be accompanied by abdominal cramps. Fever may be absent or mild. Symptoms usually occur within 2-3 days following exposure, but may occur as soon as 1 day following exposure or up to one week following exposure. Healthy adults can typically recover completely from E. coli O157:H7 exposure within a week. However, some people, especially young children and the elderly, can develop Hemolytic Uremic Syndrome (HUS) as a result of exposure to E. coli O157:H7, a condition that can lead to serious kidney damage and even death.

- **What does FDA advise people to do?**

Currently, the FDA advises that people not eat any fresh spinach or salad blends containing fresh spinach that are consumed raw. Individuals who believe they may have experienced symptoms of illness after consuming fresh spinach or salad blends containing fresh spinach are urged to contact their health care provider.

- **What is an outbreak?**

An outbreak is defined by the CDC as two (2) or more cases of the same disease are related to a common exposure.

- **In what states have illnesses been reported?**

To date, the states that have reported illnesses include: California, Connecticut, Idaho, Indiana, Kentucky, Maine, Michigan, Minnesota, Nevada, New Mexico, New York, Ohio, Oregon, Pennsylvania, Utah, Virginia, Washington, Wisconsin, and Wyoming. The implicated product was also distributed to Canada and Mexico. This outbreak is ongoing, therefore the number of illnesses and states involved may continue to increase.

- **What company and brands are included in the current recall?**

Natural Selection Foods, LLC, of San Juan Bautista, California, is recalling all of its products that contain fresh spinach in all the brands they pack with "Best if Used by

Dates" of August 17, 2006 through October 1, 2006. Products include fresh spinach and any salad blend containing fresh spinach. Products that do not contain fresh spinach are not part of this recall.

Natural Selection Foods, LLC brands include: Natural Selection Foods, Pride of San Juan, Earthbound Farm, Bellissima, Dole, Rave Spinach, Emeril, Sysco, O Organic, Fresh Point, River Ranch, Superior, Nature's Basket, Compliments, Trader Joe's, Ready Pac, Jansal Valley, Cheney Brothers, Coastline, D'Arrigo Brothers, Green Harvest, Mann, Mills Family Farm, Premium Fresh, Pro-Mark, Snoboy, The Farmer's Market, Tanimura & Antle, President's Choice, Cross Valley, and Riverside Farms.

Another company, River Ranch, of California, is currently recalling its spring mix containing spinach. River Ranch obtained bulk spring mix containing spinach from Natural Selections. The following brands are involved: Farmers Market, Hy Vee, Fresh and Easy.

- **When was the onset of the first illness related to this outbreak?**

The first illness connected to this outbreak thus far began on August 2, 2006, although most illnesses reported to date cluster with onsets from August 26 - September 9, 2006.

- **What advice does FDA have for the industry?**

Commercial food establishments should not sell fresh spinach or salad blends containing fresh spinach to consumers. Nor should food establishments utilize fresh spinach or salad blends containing fresh spinach as an uncooked ingredient in food products to be consumed by their customers. Commercial food establishments should also avoid opening and minimize the handling of fresh spinach and other fresh spinach containing products to prevent the potential for cross contamination of other foods and food-contact surfaces.

- **Who is working on this outbreak?**

FDA continues to work closely with the U.S. Centers for Disease Control and Prevention (CDC) and state and local health departments to determine the cause and scope of this outbreak.

- **Is the government conducting tests?**

Yes. The federal (principally CDC and the FDA) and state governments are working together to analyze samples from ill persons and product samples in an attempt to quickly identify the source(s) of the outbreak.

The outbreak strain of E. coli O157:H7 from ill persons is being "fingerprinted" at public health laboratories around the country, as part of PulseNet (the network of public health laboratories that sub-type bacteria). All E. coli O157:H7 strains associated with this outbreak have the same "fingerprint" (DNA pattern).

The states are collecting and analyzing samples of suspect foods. FDA has offered assistance to the states analyzing such samples as needed.

- **What steps has FDA taken to reduce the potential for outbreaks, specifically E. coli O157:H7 outbreaks, associated with raw produce?**

The FDA developed the Lettuce Safety Initiative in response to recurring outbreaks of E. coli O157:H7 in lettuce. The primary goals of the initiative are to reduce public health risks by focusing on the product, agents and areas of greatest concern and to alert consumers early and respond rapidly in the event of an outbreak. On August 24, 2006, the State of California Department of Health Services and Department of Food and Agriculture and the FDA met with industry and academia to further clarify the goals, objectives and the next steps for the Lettuce Safety Initiative. This meeting was facilitated by the Western Institute for Food Safety and Security. This initiative is based

on the 2004 Produce Safety Action Plan, intended to minimize the incidence of food borne illness associated with the consumption of fresh produce.

Since 1995, there have been 19 outbreaks of foodborne illness caused by E. coli O157:H7 for which lettuce or leafy greens were implicated as the outbreak vehicle. Although tracebacks to growers were not conducted (or "not conclusive") in all of the outbreak investigations, a majority of the outbreaks, including the recent outbreak in September of 2005, traced product back to California, many of which were from the Salinas Valley, though not exclusively.

- **Does the FDA's advice not to eat any fresh spinach or salad blends containing fresh spinach apply to both organic and non-organic products?**

Yes.

- **Can people cook the fresh spinach or salad blends containing fresh spinach?**

As stated above, the FDA is currently recommending that the public not consume fresh (uncooked) spinach or salad blends containing fresh spinach. However, E. coli O157:H7 in spinach can be killed by cooking at 160 degrees Fahrenheit for 15 seconds. If consumers choose to cook the spinach they should follow these cooking instructions and also remember to take steps to avoid cross-contamination of the fresh spinach with other foods and food contact surfaces and to wash hands, utensils, and surfaces with hot, soapy water before and after handling the spinach.

- **Have there been previous outbreaks involving fresh spinach?**

Yes. A previous outbreak involving fresh spinach occurred in California in October of 2003. Sixteen (16) cases of illness were reported and two (2) people died. The causative agent was E. coli O157:H7.

- **When did FDA first receive information regarding the current outbreak?**

FDA first became aware of the current outbreak on September 13, 2006. FDA will continue to release additional information as it becomes available.

The following questions and answers were added on September 20, 2006

- **Where in the farm to table continuum is fresh produce most likely to become contaminated? What are the potential sources for produce contamination?**

FDA's 1998 [Guide to Minimize Microbial Contamination of Fresh Fruits and Vegetables](#) (also referred to as the Good Agricultural Practices (GAPs) guide) describes potential sources of microbial contamination in the field and packing house environments and makes broad scope recommendations for how to reduce or minimize opportunities for contamination.

According to the GAPs guide, areas that should be considered to minimize the potential for the microbial contamination of produce include: agricultural water (e.g., for irrigation or crop protection sprays); wild and domestic animals; worker health and hygiene; the production environment (use of manure, previous land use, and use of adjacent land); post harvest water quality (water used to wash or cool produce) and sanitation of facilities and equipment. Our experience in outbreak investigations since 1998 points to the importance of these areas as being significant to avoid contamination of fresh produce at the farm or packinghouse. We also know that there is still a substantial need for additional produce safety research.

FDA focused on the farm and packing facilities because of a need to raise awareness about food safety at these stages of the supply chain. FDA's 2004 Produce Safety Action Plan, however, recognizes that contamination can happen at any point in the supply chain.

- **How is the cause or source of an E. coli O157:H7 outbreak determined?**
In the current spinach E. coli O157:H7 outbreak, the fact that illnesses are so dispersed (over 21 states to date) suggests that the contamination likely happened early in the distribution chain. The investigation into the possible source and cause of contamination is ongoing, including on the farm and in processing plants.
- **Does FDA issue assignments to sample and test domestic and foreign produce?**
FDA regularly issues assignments to sample both domestic and foreign fresh produce items. Reports of those assignments are posted on FDA's website.
- **Has FDA conducted outreach/education activities regarding fresh produce safety?**
FDA has the lead for foreign GAPs education/outreach and has been working with a number of food safety partners in other countries, and in the U.S., on a variety of programs targeted at the safety of fresh produce. FDA's produce safety action plan, instituted in 2004 and ongoing, contains four main objectives and many specific milestones to address produce safety, including outreach and education activities. Additionally, FDA has been distributing information materials in English and Spanish on the safe handling of raw produce and fruit and vegetable juices to health educators, state and local health agencies. FDA in conjunction with the Produce Marketing Association and the Partnership for Food Safety Education developed a multi-faceted national produce handling education campaign. Launched two years ago, this education program utilizes the media, food safety advocates and Partnership members to communicate safe handling recommendations about produce to consumers.

The following questions and answers were added or updated on September 22, 2006

- **Where was the spinach grown?**
The FDA, in working closely with the CDC and the State of California, has determined that the spinach implicated in the outbreak was grown in the following California counties: Monterey, San Benito, and Santa Clara. Other produce grown in these counties is not implicated in this outbreak. Processed spinach (e.g., frozen and canned spinach) is also not implicated in this outbreak.
- **In what states have illnesses been reported? Updated**
To date, the states that have reported illnesses include: Arizona, California, Colorado, Connecticut, Idaho, Illinois, Indiana, Kentucky, Maine, Michigan, Minnesota, Nebraska, Nevada, New Mexico, New York, Ohio, Oregon, Pennsylvania, Utah, Virginia, Washington, Wisconsin, and Wyoming. The implicated product was also distributed to Canada, Mexico, Taiwan, Hong Kong and Iceland. No illnesses have been reported from these countries.

This outbreak is ongoing, therefore the number of illnesses and states involved may continue to increase.
New Mexico's public health laboratory has isolated E. coli O157:H7 from a package of spinach. The package came from the refrigerator of a patient who ate some of the spinach before becoming ill. The New Mexico laboratory completed "DNA fingerprinting" tests. New Mexico and CDC determined that the "DNA fingerprint" matches that of the outbreak strain.
- **What companies and brands are included in the voluntary recalls issued as a result of the current outbreak? Updated**
On 9/15/06, Natural Selection Foods, LLC, of San Juan Bautista, California announced a voluntary recall of all products that contain fresh spinach with "Best if Used by Dates"

of August 17, 2006 through October 1, 2006. (See additional information about brands associated with Natural Selection Foods below). Other companies and brands of fresh spinach and fresh spinach containing products may also be involved in this outbreak; FDA and CDC continue to investigate this possibility.

Natural Selection Foods, LLC brands include: Natural Selection Foods, Pride of San Juan, Earthbound Farm, Bellissima, Dole, Rave Spinach, Emeril, Sysco, O Organic, Fresh Point, River Ranch, Superior, Nature's Basket, Compliments, Trader Joe's, Ready Pac, Jansal Valley, Cheney Brothers, D'Arrigo Brothers, Green Harvest, Mann, Mills Family Farm, Premium Fresh, Pro-Mark, Snoboy, The Farmer's Market, Tanimura & Antle, President's Choice, Cross Valley, and Riverside Farms.

On 9/17/06, another company, River Ranch, of California, announced a voluntary recall of spring mix containing spinach. River Ranch obtains bulk spring mix containing fresh spinach from Natural Selections for processing and packaging. **UPDATED** The following brand names are included in the River Ranch recall: Fresh N' Easy Spring Mix and Hy-Vee Spring mix containing baby spinach, distributed to retailers in Texas, Iowa, New Mexico, Georgia and Ohio. The River Ranch product included in the recall is packed in 5 oz. bags and 5 oz. plastic trays.

On 9/19/06 RLB Food Distributors of West Caldwell, New Jersey, announced a voluntary recall that may contain spinach from Natural Selection Foods. All the products recalled by RLB have an "Enjoy Thru date of 9/20/06 or before." The products are: Balducci's Mesclun Mix, Balducci's Organic Baby Spinach, Balducci's Mixed Greens, FreshPro Mesclun Mix, FreshPro Organic Baby Spinach, FreshPro Mixed Greens, FreshPro Salad Mix with Italian Dressing, and FreshPro Salad Mix with Ranch Dressing. The recalled products were distributed in Connecticut, New York, New Jersey, Pennsylvania, Maryland, Delaware, Virginia and Washington DC.