



THE FOOD AND DRUG ADMINISTRATION / AN AGENCY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FDA Announces Findings from Investigation of Foodborne *E. coli* O157:H7 Outbreak in Spinach

FDA is announcing today that all spinach implicated in the current outbreak has traced back to Natural Selection Foods LLC of San Juan Bautista, California. This determination is based on epidemiological and laboratory evidence obtained by multiple states and coordinated by the Centers for Disease Control and Prevention. Natural Selection Foods issued a recall of all implicated products on September 15, 2006. Four other companies have issued secondary recalls because they received the recalled product from Natural Selections. See below for a complete list of brand names that are subject of the recalls. Spinach processed by other manufacturers has not been implicated in the outbreak.

FDA, the State of California, the Centers for Disease Control and Prevention and the United States Department of Agriculture continue to investigate the cause of the outbreak. This includes continued inspections and sample collection in facilities, the environment and water, as well as studies of animal management, water use and the environment.

Next Steps

Although the current outbreak may ultimately trace back to a specific field(s), there has been a long history of *E. coli* O157:H7 outbreaks involving leafy greens from the central California region. Spinach processed by other manufacturers has not been implicated in this outbreak, however, based on discussions with industry, and given the past *E. coli* O157:H7 outbreaks, FDA and the State of California expect the industry to develop a comprehensive plan which is designed to minimize the risk of another outbreak due to *E. coli* O157:H7 in spinach grown in central California. While this plan is under development, FDA and the State of California reiterate our previous concerns and advise firms to review their current operations in light of the agency's guidance for minimizing microbial food safety hazards.

FDA and the State of California have previously expressed serious concern with the continuing outbreaks of foodborne illness associated with the consumption of fresh and fresh-cut lettuce and other leafy greens. After discussions with industry, FDA and the State of California, as part of a longer term strategy, now expect industry to develop a plan to minimize the risk of another outbreak due to *E. coli* O157:H7 in all leafy greens, including lettuce.

The Grower Shipper Association of Central California, the Produce Marketing Association, the United Fresh Produce Association, and the Western Growers Association, said today, "We are committed to working together as one industry to learn everything we can from this tragedy, and will redouble our efforts to do everything in our power to reduce the potential risk of foodborne illness. As we have in the past, we will work aggressively with the Food and Drug Administration and state regulatory authorities to ensure the industry's growing and processing practices continue to be based on the very best scientific information available, and that we are doing everything possible to provide the nation with safe and healthy produce."

Implementation of these plans will be voluntary, but FDA and the State of California are not excluding the possibility of regulatory requirements in the future.

FDA will be holding a public meeting to address the larger issue of food borne illness linked to leafy greens later in the year once the current investigation is complete.

Advice to Retailers, Restaurateurs and the Public

FDA is still reminding the public that Natural Selection Foods has recalled all spinach products under multiple brand names with a date code of October 1 or earlier. There have been four other recalls from different companies because they received Natural Selection Foods spinach. See below for a complete list of brand names that are subject of the recalls.

In order to protect consumers, **retailers and restaurateurs** should not sell raw spinach or blends that may contain spinach that was processed by Natural Selection Foods and all other brands subject to the recalls.

Consumers are advised that proper storage of fresh produce can affect both quality and safety. To maintain quality of fresh produce, certain perishable fresh fruits and vegetables (like strawberries, lettuce, herbs, and mushrooms) can be best maintained by storing in a clean refrigerator at a temperature of 40° F or below. All produce that is purchased pre-cut or peeled should be refrigerated to maintain both quality and safety.

Many pre-cut, bagged produce items like lettuce are pre-washed. If so, it will be stated on the packaging. This pre-washed, bagged produce can be used without further washing.

Processed spinach (e.g., frozen and canned spinach) is not implicated in this outbreak.

Number of Cases of Infection, Hospitalization and Death

To date, **187** cases of illness due to *E. coli* O157:H7 infection have been reported to the Centers for Disease Control and Prevention (CDC), including **29** cases of Hemolytic Uremic Syndrome (HUS), **97** hospitalizations and one death.

States Involved and Number of Cases

The 26 affected states are: Arizona (7), California (2), Colorado (1), Connecticut (3), Idaho (4), Illinois (1), Indiana (9), Kentucky (8), Maine (3), Maryland (3), Michigan (4), Minnesota (2), Nebraska (9), Nevada (1), New Mexico (5), New York (11), Ohio (25), Oregon (6), Pennsylvania (9), Tennessee (1), Utah (17), Virginia (2), Washington (3), West Virginia (1), Wisconsin (49), and Wyoming (1). In addition, Canada has one confirmed case.

Laboratory Findings

There are now a total of **10** confirmed product samples that contain the *E. coli* O157:H7 outbreak strain.

- The Colorado Department of Public Health and Environment has confirmed the presence of the outbreak strain of *E. coli* O157:H7 in a sample of Dole spinach with a lot code of P227A02, and a “best if used by” date of August 30, 2006.
- The Ohio Department of Health confirmed the isolation of *E. coli* O157:H7, matching the outbreak strain, from a package of bagged spinach.
- The Wisconsin Department of Health and Family Services has confirmed that *E. coli* O157:H7, the same strain as that associated with the outbreak, has been found in 2 bags of Dole Baby Spinach with lot codes of P227A.
- The Nevada Department of Health and Human Services has reported a confirmed finding of *E. coli* O157:H7 in bagged spinach, matching the outbreak strain. The Nevada sample was analyzed by FDA Pacific Regional Lab NW.
- The Pennsylvania Department of Health has confirmed that *E. coli* O157:H7, the same strain as that associated with the outbreak, has been found in 2 individual bags of Dole spinach purchased in Pennsylvania with a “best if used by” date of August 30, 2006, and a lot code of P227A01.
- The Utah Department of Health (UDOH) and the Salt Lake Valley Health Department (SLVHD) have confirmed that *E. coli* O157:H7, the same strain as that associated with the outbreak, has been found in a bag of Dole Baby Spinach purchased in Utah, with a lot code of P227A01. Laboratory tests were conducted by the Utah Public Health Laboratory (UPHL).
- The New Mexico Department of Health announced on September 20, 2006, that it had linked a sample from a package of spinach with the outbreak strain of *E. coli* O157:H7. DNA fingerprinting tests determined that the strain from the spinach matches the strain from patients in the outbreak. The package of spinach that tested positive was Dole Baby Spinach, with a lot code of P227A03.
- The Illinois Department of Public Health has confirmed that *E. coli* O157:H7, matching the outbreak strain, has been found in a package of Dole Fresh Spinach with a lot code of P227A02, and a “best if used by” date of August 30.

Product Recalls (5)

To date, 5 firms have initiated recalls:

1) On September 22, 2006, Pacific Coast Fruit Company of Portland, Oregon initiated a voluntary recall of products that may include spinach supplied by Natural Selections Foods. Pacific Coast Fruit Company stopped making all products with spinach supplied from California on September 14, 2006. The recalled products are:

Baby Spring Mix Salad Kit (4.6 lbs), Chef on the Run- Bacon Spinach Salad (9 oz. plus 2 fl. oz. dressing), Chef on the Run - Spring Greens Salad (5 oz. plus 2 fl. oz. dressing), Chef on the Run - Willamette Valley Salad (10 oz. plus 2 fl. oz. dressing), Trader Joe's - Baby Spinach and Greens with Bleu Cheese, Candied Pecans and Cranberries with Raspberry Vinaigrette Dressing (10 oz.), Trader Joe's - Baby Greens and Spinach Salad with Wild Maine Blueberry Dressing (10 oz.), Mediterranean Veggie Blend Kit - 15 lbs, and My Brothers Pizza Spinach and Garlic - 15 oz. and 36 oz.

Most of the salad products can be identified by the labels Trader Joe's, My Brothers Pizza or Chef on the Run and are in clam shell containers. Pizza products are in round cardboard bottoms with a plastic over wrap. All salad products will have a "USE BY DATE" on or before Sept 20, 2006. Pizza products will have a "USE BY DATE" on or before September 23, 2006. The products were distributed through various retail outlets in Alaska, Oregon, Washington and Idaho. There is no international distribution.

2) On September 22, 2006, Triple B Corporation, doing business as S.T. Produce, of Seattle, Washington, initiated a voluntary recall of its fresh spinach salad products with a "Use By" date of 8/22/2006 thru 9/20/2006. Spinach used in these products may have been supplied from Natural Selections Foods of California. The recalled products were distributed in Washington, Oregon, Idaho and Montana to retail stores and delis and sold in a hard plastic clamshell container.

The products recalled by S.T. Produce are: NWG Spinach Salad (5 oz.), Spinach Salad, QFC (5 oz.), Charlie's Spinach Salad (5 oz.), Charlie's Tabouli & Goat Cheese Salad (10 oz.), NWG Tabouli & Goat Cheese Salad (10 oz.), Tabouli & Goat Cheese Salad, QFC (10 oz.), T/H Spring Mix Salad (5.5 oz.), T/H Mozzarella Spring Mix Salad (5.5 oz.), T/H Baby Spinach Salad (5.5 oz.), Walnut and Blue Cheese Salad w/ Grilled Chicken Breast (6.5 oz.), Larry's Market Tabouli & Goat Cheese Salad (10 oz.), Charlie's Seasonal Greens Salad (2.5 oz.), Charlie's Seasonal Greens Salad (4 oz.), Charlie's Baby Spinach Salad (6 oz.), Charlie's Baby Spinach Salad (5 oz.) and Caesar Bowtie Noodle Salad Kit with Grilled Chicken Breast (6.9 lbs).

3) On September 19, 2006, RLB Food Distributors, L.P., West Caldwell, NJ, initiated a voluntary recall of certain salad products that may contain spinach with an 'Enjoy Thru' date of 9/20/06.

The products recalled by RLB are: Balducci's Mesclun Mix 5 oz., Balducci's Organic Baby Spinach 5 oz., Balducci's Mixed Greens 5 oz., FreshPro Mesclun Mix 5 oz., FreshPro Organic Baby Spinach 5 oz., FreshPro Mixed Greens 5 oz., FreshPro Salad Mix with Italian Dressing 4.75 oz., and FreshPro Salad Mix with Ranch Dressing 5.25 oz.

4) On September 17, 2006, River Ranch, of Salinas, California, announced a voluntary recall of packages of spring mix containing spinach. River Ranch obtained bulk spring mix containing spinach from Natural Selections. The following brands are involved: Fresh N' Easy Spring Mix and Hy-Vee Spring mix containing baby spinach, distributed to retailers in Texas, Iowa, New Mexico, Georgia and Ohio. Product was packed in 5 oz. bags and 5 oz. plastic trays. Products that do not contain spinach are not part of this recall.

5) On September 15, 2006, Natural Selection Foods, LLC, of San Juan Bautista, California, announced a voluntary recall of all 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, D'Arrigo Brothers Co. of New York, 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, Mexico, Taiwan, Hong Kong and Iceland. FDA continues to investigate whether other companies and brands are involved.

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.

Lettuce Safety Initiative

The FDA developed the Lettuce Safety Initiative 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.

Additional Information

FDA continues to work closely with the CDC and state and local agencies to determine the cause and scope of the *E. coli* O157:H7 outbreak in spinach. Please check www.fda.gov for updates.

Additional information regarding safe handling of raw produce and fresh-squeezed fruit and vegetable juices can be found at <http://www.cfsan.fda.gov/~dms/prodsafe.html>.

For additional general food safety tips, go to www.fightbac.org.

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