The Food Industry Center

UNIVERSITY OF MINNESOTA

NATIONAL CENTER FOR FOOD PROTECTION AND DEFENSE
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Natural Selection: 2006 *E. coli* Recall of Fresh Spinach
A Case Study by The Food Industry Center

October 2009

This case summarizes the 2006 fresh spinach recall and questions prompted by one of the largest outbreaks of foodborne illness in the United States in recent years — an estimated 4,000 cases. While every food recall is important and unique, the contamination of fresh spinach with the bacteria *Escherichia coli* (*E. coli*) O157:H7 during the summer and fall of 2006 and the breadth of the recall and the severity of the consequences from *E. coli* O157:H7 lend themselves to this exemplary case study. This study also helps illustrate the complexity of the food supply chain and the food recall process. A similar incident, involving fresh tomatoes and peppers rather than spinach, and *Salmonella* rather than *E. coli*, occurred in the spring and summer of 2008. It is explored briefly at the end of this case study.[1]

USDA

 This case was prepared by Jon Seltzer, marketing instructor at the University of St. Thomas and consultant to The Food Industry Center, Jeff Rush, research assistant, and Jean Kinsey, Director of The Food Industry Center. This case was developed under a grant from the National Center for Food Protection and Defense, a Department of Homeland Security Center of Excellence funded by U.S. Department of Homeland Security Science and Technology Assistance Agreement No. 2007-ST- 061-000003. It has not been formally reviewed by the Department of Homeland Security. The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies, either expressed or implied, of the Department of Homeland Security. The Department of Homeland Security does not endorse any products or commercial services mentioned in this publication.

[1] This case is the second in a series of three food recall cases. Castleberry's 2007 botulism recall was the subject of the first. A third is on the ground beef industry.

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Introduction

The contamination of fresh spinach with the bacteria *Escherichia coli (E. coli)* O157:H7 during the fall of 2006 led to one of the largest outbreaks of foodborne illness in recent years.[2] The complexity of the supply chain and subsequent recall can be summarized by the number of companies and brands involved. Spinach harvested by Mission Organics at the Paicines Ranch in central California, processed by Natural Selection Foods doing business as Earthbound Farm, and packed mostly into bags of Dole Baby Spinach was shipped nationwide and carried *E. coli* O157:H7 into the homes of consumers.[3]

Most of the illnesses occurred from August 26, 2006, to September 16, 2006. Illnesses were confirmed in 26 states, as well as Ontario, Canada. In all, 205 cases of illness were recorded, including 31 involving a type of kidney failure called hemolytic uremic syndrome (HUS). More than 100 people were hospitalized, and three deaths were officially recorded.[4] Two more deaths might have also been caused by the contaminated spinach, but they were not confirmed.[5] The Centers for Disease Control and Prevention (CDC) estimated 4,000 people were sickened because likely only 5 percent of the illnesses were reported.[6]

> *"One foodborne illness is too many. We've seen that there is no such thing as a small error when it comes to produce safety. Even what may be perceived as a small error can have disastrous consequences*."[7] (Robert Brackett, then Director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN) who later went on to become Chief Science Officer of the Grocery Manufacturers Association (GMA).

Each year in the United States, the CDC estimates 76 million people get sick, more than 325,000 are hospitalized, and 5,000 people die from foodborne illness.[8]

Fresh produce is vulnerable to contamination because it is usually grown outdoors and is often consumed raw, without cooking or other treatments that can destroy bacteria and other pathogens.[9] This outbreak was among 24 associated with leafy greens since 1996. Of the 12 *E. coli* O157:H7 outbreaks that were traced, all came from California. Most were traced to fields in the Salinas Valley, known as "America's Salad Bowl."[10]

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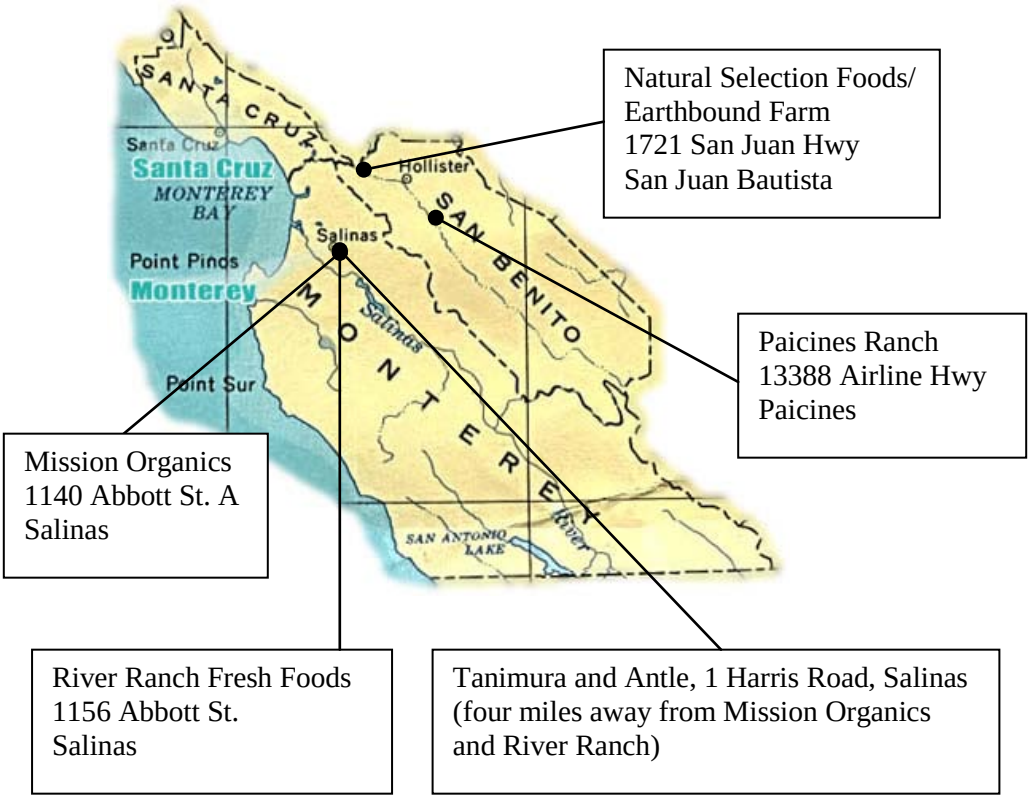
[2] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[3] USA Today, "Five Faces, Five Agonizing Deaths, One Year Later," September 21, 2007
[4] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[5] USA Today, "Five Faces, Five Agonizing Deaths, One Year Later," September 21, 2007
[6] Los Angeles Times, "Tainted Spinach Tied to Cattle Ranch," March 24, 2007
[7] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[8] CDC www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm#howmanycases
[9] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[10] FDA, "E. coli O157:H7 Spinach Outbreak 2006" Public Meeting, March 20, 2007

FIGURE 1: The Salinas Valley: America's Salad Bowl



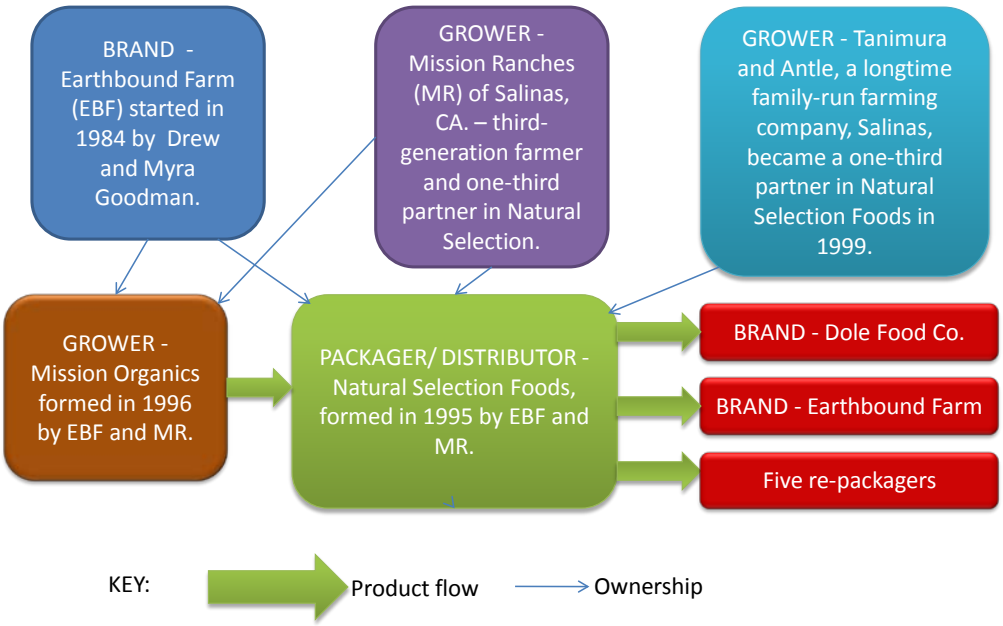
The Salinas Valley, located about 100 miles south of San Francisco and 300 miles north of Los Angeles, is the center for Monterey County's multibillion-dollar agriculture industry.

Because of its temperate climate and fertile soil, Monterey County is the top vegetable-producing region in the nation and supplies 80 percent of the nation's lettuce. The county also supplies 80 percent of the nation's artichokes. Broccoli, cauliflower, spinach, strawberries, peppers, squash, carrots, asparagus, celery, tomatoes, mushrooms, brussels sprouts, garlic, onions and flowers are also grown here in abundance.

Additionally, Monterey County exports more than 580 million pounds of produce annually. Top importers of Salinas Valley produce include Canada, Japan, Hong Kong, Taiwan, Mexico and the European Union.

Source: Salinas Valley Chamber of Commerce

FIGURE 2: Directly Involved: Natural Selection, Earthbound Farm, Mission Organics and Dole Food Company



Highly Interrelated Companies

While many brands were affected by this recall, four companies — Natural Selection Foods, Earthbound Farm, Mission Organics, and Dole were primarily involved. The first three companies are highly interrelated. The resulting mix of companies grows, packages, and distributes produce. In addition to running fields of their own, they contract with others to supply produce to them.

Natural Selection Foods of San Juan Bautista, CA, describes itself as "North America's leading supplier of specialty salads." The company was formed in 1995 when the founders of organic produce brand Earthbound Farm partnered with third-generation family farmers Mission Ranches of Salinas, CA. In 1999, Tanimura and Antle, another longtime family-run farming company, also of Salinas, became a one-third partner in the company. Natural Selection is the packager and distributor of the Earthbound Farm brand of organic produce, baked goods, and beverages.[11]

Earthbound Farm was started in 1984 by Manhattan transplants Drew and Myra Goodman, who went to college in California and stayed. They started with 2.5 acres of organic raspberries and greens and a roadside farm stand[12] and, according to the company website, in 1986 became the first company to successfully launch prewashed, packaged salad for retail sale. "When we

[11] Natural Selection Foods www.nsfoods.com/
[12] Washington Post, "From Roadside Stand to Produce Empire; Until E. coli Outbreak, Natural Selection Foods Was a Model of Farming Achievement," September 22, 2006

introduced our mixed baby greens or "spring mix" to restaurants and supermarket produce aisles, we started a salad revolution," the company's website says. "Today, gourmet salad greens and packaged salads have become staples of grocery baskets everywhere." The company calls itself the world's largest grower of organic produce.[13]

Mission Organics' Otto Kramm, Chief Executive Officer, co-founded Mission Organics with Mission Ranches and Earthbound Farm in 1996. Before the outbreak, Mission Organics farmed about 6,000 acres in California and supplied everything it grew directly to Natural Selection. After the outbreak, Kramm said, Natural Selection reduced its orders for Spinach from Mission Organics. A spokeswoman for Natural Selection said she did not know whether orders for spinach or other leafy greens from Mission Organics had been reduced.[14]

Dole Food Company, which calls itself the world's largest producer and marketer of high-quality fresh fruit and fresh vegetables, was founded in Hawaii in 1851 and is now headquartered in Westlake Village, CA outside Los Angeles. The company also markets a growing line of packaged and frozen foods.[15]

Natural Selection is the packager and distributor of the Earthbound Farm brand. Together, they are both a grower and a processor, operating fields of their own and partnering with others. They have grown by operating as a link between individual farmers and supermarket chains, according to Bob Scowcroft, Executive Director of the Organic Farming Research Foundation in Santa Cruz, CA.[16] They work up and down the West Coast, including Mexico and Chile, so produce can be picked continuously.[17] Earthbound Farm ships produce from San Bautista, CA, from spring through fall, and from Yuma, AZ, from approximately Thanksgiving through Easter.[18]

TABLE 1: Company Numbers

	Year established	Most recent employee count	Most recent est. annual sales
Natural Selection	1995	1,025	$67 million
Earthbound Farm	1984	50	$4.1 million
Mission Organics	1996	200	$43 million
Dole	1851	75,000	$6.9 billion

Sources: 2009 Dun & Bradstreet Million Dollar Database, Global Duns Market Identifiers, company websites

[13] Earthbound Farm www.ebfarm.com/aboutus/index.aspx
[14] The Salinas Californian, "Grower Details His Side of Outbreak," March 19, 2007
[15] Dole Food Company www.dole.com
[16] Washington Post, "From Roadside Stand to Produce Empire; Until E. coli Outbreak, Natural Selection Foods Was a Model of Farming Achievement," September 22, 2006. The Organic Farming Research Foundation receives some financial support from Earthbound Farm.
[17] Washington Post, "From Roadside Stand to Produce Empire; Until E. coli Outbreak, Natural Selection Foods Was a Model of Farming Achievement," September 22, 2006
[18] Earthbound Farm, www.ebfarm.com/Trade/ShippingInformation.aspx

Produce Distribution Practices

U.S. restaurants and grocery stores often buy produce from the same major food processors, sometimes under the same label, but most often under different labels. The produce a consumer purchases in a grocery store might be processed by the same company as that in a restaurant.[19] This label flexibility enables sellers to provide a consistent retail presence by sourcing product from multiple growing regions in response to market demand and weather-induced supply. As most retailers commit to their print ads six weeks in advance, the ability to pack-on-demand makes it possible to promote highly perishable short-dated products.

The down side of this process is a given brand can come from multiple processing facilities packaging multiple brands. As a result, it is more difficult to determine the source of suspect product and to confine a recall to that brand without implicating other labels.

Additionally, when wholesalers and retailers in the middle of the supply system find themselves with too much of one product in one place, they might divert it to other parts of their operation (perhaps in a different part of the country), sell it to other organizations, or even donate some product to a charitable organization. The more diversions a product takes within the food supply system, the more difficult it subsequently becomes to trace through the supply chain.

Safety Issues in Spinach Production

In the production of fresh spinach and other greens, there is no "kill step" that eliminates pathogens. The best technology, triple washing, removes 99 percent of pathogens.[20] Cooking fresh spinach at 160 degrees Fahrenheit for 15 seconds will kill any *E. coli* O157:H7 present.[21]

Fresh produce is especially vulnerable to contamination because it is primarily grown in an open environment. It is often consumed raw, without cooking or other treatments that could destroy bacteria and other pathogens.[22] FDA findings from previous leafy green investigations indicate that pre-harvest and harvest phases of production are the most likely opportunity for introduction of contamination. Contamination might come from water, manure used as fertilizer, wildlife, or workers. Postharvest practices (cooling, processing, shipping) might contribute to spreading the contamination over thousands of bags of greens and might permit growth of a contaminant organism.[23]

Representatives of the leafy greens industry noted the following as the main issues that need to be considered in growing and harvesting:[24]

> **Water:** Irrigation water and water used in harvesting must be of appropriate microbial quality. Irrigation methods must be evaluated for their potential to introduce, support, or promote the spread and growth of human pathogens. Irrigation water reservoir methods must be similarly evaluated.

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[19] CDC, "Questions and Answers about E. coli O157:H7 Outbreak from Fresh Spinach." October 12, 2006
[20] Los Angeles Times, "Stalking a Killer in Our Greens," August 13, 2007
[21] FDA Consumer, "Nationwide E. coli O157:H7 Outbreak: Questions & Answers," November-December
[22] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[23] FDA, "E. coli O157:H7 Spinach Outbreak 2006" Public Meeting, March 20, 2007
[24] International Fresh-Cut Produce Association et al, "Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain," April 25, 2006

Wellton-Mohawk Irrigation and Drainage District

Soil Amendments: Soil amendments are commonly but not always incorporated into agricultural soils to add nutrients and reduce soil compaction. Proper composting of animal manures will reduce the risk of survival of pathogens harmful to humans. Management plans must be implemented to address timing of applications, storage location, source and quality, and transport, among other things.

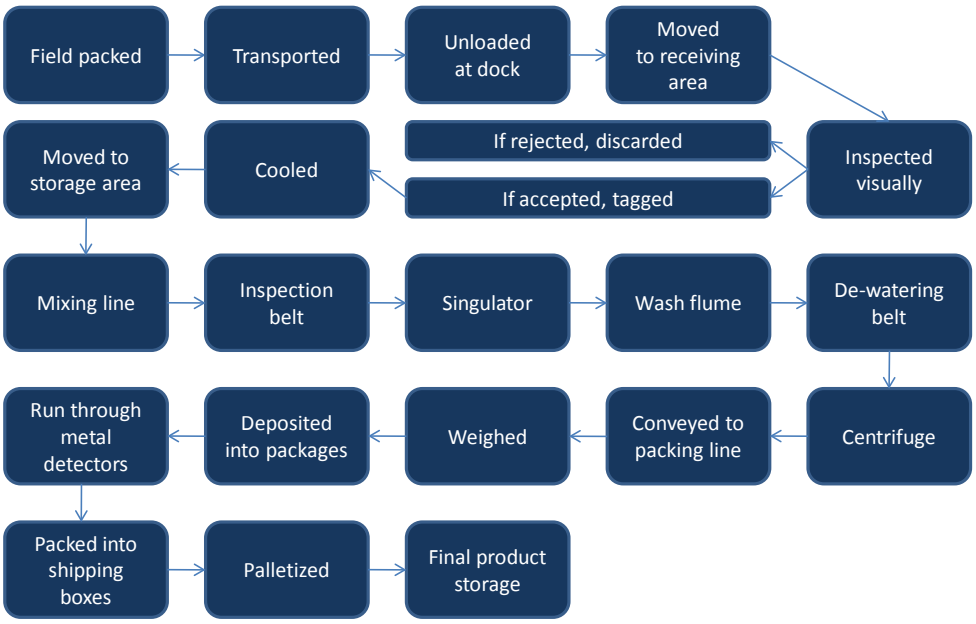
Machine Harvest: Measures must be established to reduce, control, or eliminate the potential introduction of human pathogens at the cut surface during and after mechanical harvest operations. Equipment, as well as all food contact surfaces such as tarps and conveyor belts, should be cleaned and sanitized according to Sanitation Standard Operation Procedures.

Hand Harvest: Appropriate measures include hand washing, glove use, and mandatory use of sanitary field latrines.

Animal Encroachment: Many wildlife species are known to be potential carriers of human pathogens. Both domestic and wildlife animal activity must be monitored and minimized.

Post-harvesting Issues are similar: Water must be of appropriate quality, equipment must be regularly cleaned and sanitized, and employees must maintain good hygiene. The temperature at which fresh produce is safely stored must be maintained throughout its journey from the field to the home or restaurant.

FIGURE 3: Natural Selection's Production Process Before the Outbreak



Standard Pathway to Market

Natural Selection's production process before the outbreak went something like this:

Product was field packed in either plastic totes (15 to 20 pounds) or bins (about 250 pounds). Refrigerated trucks transported product from fields both near and far to the production facility and tractors transported product from nearer fields. Product was unloaded at an outdoor loading dock and then moved to the receiving area.

There, a sample was collected from each load and inspected visually for contamination. If the product was accepted, it was given a tag with a unique number and the data for that bin or pallet (grade, product type, grower and grower lot number, harvest date, net weight and expiration date). If the product was rejected, the grower was notified and given the option to retrieve it. If the grower did not retrieve it, the product was discarded.

After inspection, the product was cooled. After cooling, the product was moved to a raw material storage area, where it was stored for up to 72 hours before reevaluation or processing. As pallets of product were removed from raw materials storage and sent to the processing lines, each pallet number was recorded by hand.

The processing sequence began with mixing lines, i.e., a conveyor belt onto which salad products were dumped. The product moved over an inspection belt, where two employees watched for

visible quality and contamination issues. Product then traveled over a singulator, used to separate the leaves so they would not enter the wash flume in clumps. Each mixing line fed a separate wash flume. Natural Selection used a two-stage wash composed of two wash flumes in sequence. The water in the flumes was re-circulated during the day and drained at the end of the day. The water in the flumes was chlorinated and pH adjusted. Product then exited the flume over a de-watering belt and was deposited into perforated plastic centrifuge barrels. The product was centrifuged and then manually dumped onto a conveyor for one of the packing lines.

Once in the packing line, the product was mechanically weighed and deposited into retail bags, retail clamshell packages, or food service bags. Packages were run through metal detectors and then packed into shipping boxes. The boxes were palletized and moved to finished product storage, where they were kept at a temperature below 41 degrees Fahrenheit.

A cleaning shift took place at the end of each day, starting at 2 a.m. and lasting about four hours. A more extensive sanitation shift took place each Sunday.[25]

What is *E. coli* O157:H7?

Escherichia coli (abbreviated as *E. coli*) are a large, diverse group of bacteria. Although most strains of *E. coli* are harmless (many live in the human intestine all the time) other strains are dangerous. Some strains of *E. coli* can cause diarrhea, while others cause urinary tract infections, respiratory illness, pneumonia and other illnesses. Some kinds of *E. coli* cause disease by making a toxin called Shiga toxin also referred to as STEC. The most commonly identified STEC in North America is *E. coli* O157:H7. Experts think there might be 70,000 *E. coli* O157 infections annually in the United States.[26]

Transmission of *E. coli* to humans from food was associated early on with contaminated ground beef. Subsequently, it has also been found to spread through unpasteurized fruit juices, leafy greens, and contaminated drinking water as well as through contact with infected animals (such as in petting zoos) and person-to-person, especially among children in day care centers.

On average, symptoms from *E. coli* O157:H7 infection develop within three to four days of eating contaminated food. Symptoms usually include severe bloody diarrhea and abdominal cramps. Usually little or no fever is present and the illness ends in five to 10 days. According to health officials antibiotics should not be used to treat the infection because treatment with antibiotics can hasten kidney complications. Antidiarrheal agents, such as loperamide (Imodium), should also be avoided. In some people (especially children and elderly), the infection can also cause a complication called hemolytic uremic syndrome (HUS), in which the red blood cells are destroyed and the kidneys fail. This condition is usually treated in an intensive care unit of a hospital. Blood transfusions and kidney dialysis are often required. With intensive care, the death rate for HUS is 3 to 5 percent.

Consumers can minimize the transmission of *E. coli* in the home by always practicing safe food handling and preparation measures. Keeping raw meat, poultry, and seafood separate from fresh produce and other ready-to-eat foods is essential. Washing hands, utensils, and surfaces with hot,

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[25] California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007
[26] Centers for Disease Control www.cdc.gov/nczved/dfbmd/disease_listing/stec_gi.html

soapy water before and after handling food is important. At the grocery store, separate raw meat, poultry, seafood, and eggs from other foods in the cart and grocery bags.[27]

What is a Recall?

A recall of any kind is complex, possibly involving multiple large companies, small retailers, levels of government and, of course, consumers. In this case, the severe danger of *E. coli* O157:H7 elevated the need for immediate, efficient response and communication.

A recall is a company's removal of distributed product from commerce when there is reason to believe that the product is adulterated or misbranded, mislabeled, or unsafely contaminated. Two federal agencies, the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA), are involved in recall administration, but do not have the legal power to order a recall. There are exceptions in cases of baby formula, biological products, or medical devices that might present a serious hazard to health. Recalls are almost always voluntary.

The FDA handles recalls of all food and food-related products except meat, poultry and eggs, which are handled by the USDA. If a food company institutes its own recall, it is generally under no obligation to notify the FDA, but it is strongly encouraged to do so and take advantage of the FDA's assistance. The FDA can request, but not mandate a recall this is generally doneonly when public health is in eminent danger. This process operates on a principle of protection after an incident.

In the case of the USDA, reports of an unsafe product can come from the manufacturer, routine testing performed by the USDA's Food Safety and Inspection Service (FSIS), or consumer complaints. FSIS field inspectors, who inspect meat, poultry, and egg processing plants on a regular basis, might come across a situation in a facility that flags potentially unsafe food. A company-initiated recall is handled similar to the FDA method, while a FSIS-initiated recall usually occurs only in instances of serious health threat. The FSIS process operates on the principle of prevention.

Recalls may originate in two ways. Sometimes a company discovers on its own there is a problem with a product and institutes its own corrective recall. Other times, a routine inspection visit or test by the FDA or a USDA inspector will discover a problem and they inform the company. At that point, if the company does not start a recall process, the product may be seized via court action and the media notified. In the case of USDA-inspected companies, inspectors are withdrawn from the plant, effectively banning the product from interstate commerce. Both the FDA and the USDA can order a factory to close or refer it for criminal prosecution.

The CDC has a complementary role, serving as the lead federal agency for conducting disease surveillance and outbreak investigations. Surveillance systems coordinated by the CDC, in collaboration with the states, provide an essential early-information network to detect dangers in the food supply.[28]

FDA and the USDA guidelines categorize all recalls into one of three classes according to the level of hazard involved: **Class I recalls** are for dangerous or defective products that predictably could cause serious health problems or death. **Class II recalls** are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. **Class III recalls** are for

[27] CDC, "Questions and Answers about E. coli O157:H7 Outbreak from Fresh Spinach." October 12, 2006
[28] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007

products that are unlikely to cause any adverse health reaction, but violate federal labeling or manufacturing regulations.

With all food recall situations, the overseeing government agency expects a company to have a recall plan, with such elements as:

—Identification of recall personnel
—Evaluation of health hazards
—Depth of recall
—Public notification
—Returned product control and disposition
—Recall procedures
—Scope of recall
—Recall communication
—Effectiveness checks
—Recall simulations

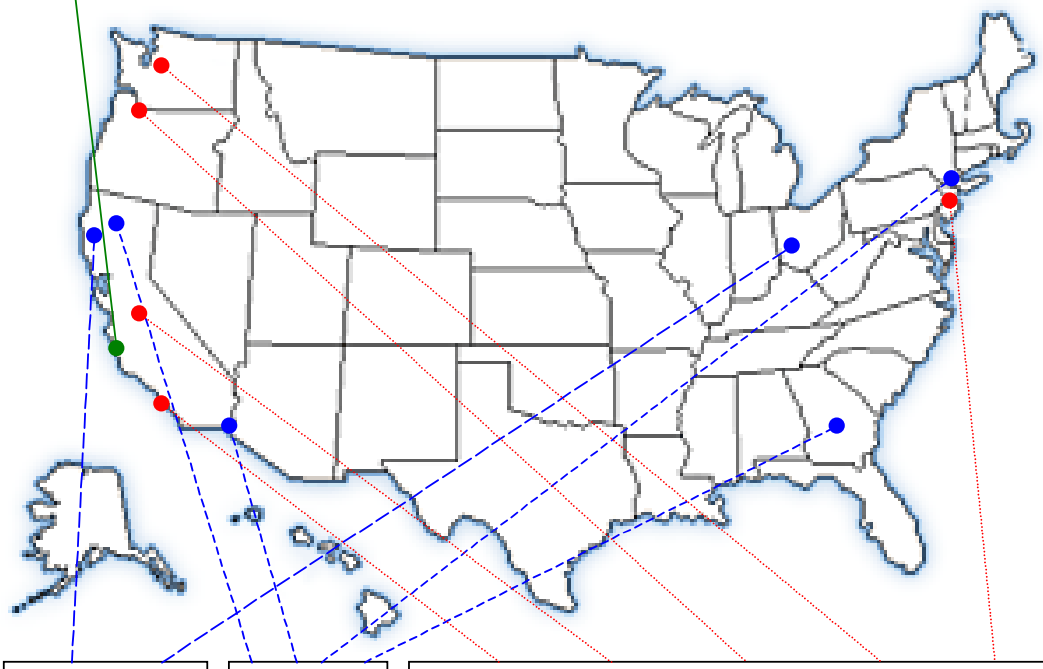
Even in a best-case scenario, however, when a company has planned well and communicates the recall well, there are difficult hurdles because of the complexity of the food supply system. Food takes many routes to get from producers to consumers. As organizations in the middle of the supply system find themselves with too much of one product in one place, they might divert it to other parts of their operation (perhaps in a different part of the country), sell it to other organizations, or even donate some product to a charitable organization. The more twists and turns a product takes within the food supply system, the more difficult it becomes to track, and the more vital the UPC product codes become. For the purposes of a recall, citing information such as brand names, use-by dates, and manufacturer production codes often causes confusion.

Barry Eisenberg, Vice President of Technical Services for **River Ranch**, one of the companies that recalled spinach-containing products, took a broad approach to the recall since specific field information was not immediately available. "It just got very confusing," he said. His company became part of the recall because its spring mix contained spinach from Natural Selection. He said everyone who handled spinach from Natural Selection "was guilty by association from our customers' viewpoint."[29]

[29] Interview Barry Eisenberg, River Ranch vice president of technical services, October 29, 2008

FIGURE 4: Natural Selection-Related Spinach Recalls

1) Spinach was harvested by Mission Organics at the Paicines Ranch in **Paicines, CA.** Natural Selection, doing business as Earthbound Farm, produced Dole brand Baby Spinach with product code P227A in **San Juan Bautista, CA,** and packed and shipped it to Dole distribution centers between noon August 15, 2006, and 5 a.m. August 16, 2006.



2) Dole distribution centers in **Marin, CA**, and **Springfield, OH,** received the P227A Baby Spinach and sent it to subdistributors and other locations throughout the United States and Ontario, Canada.

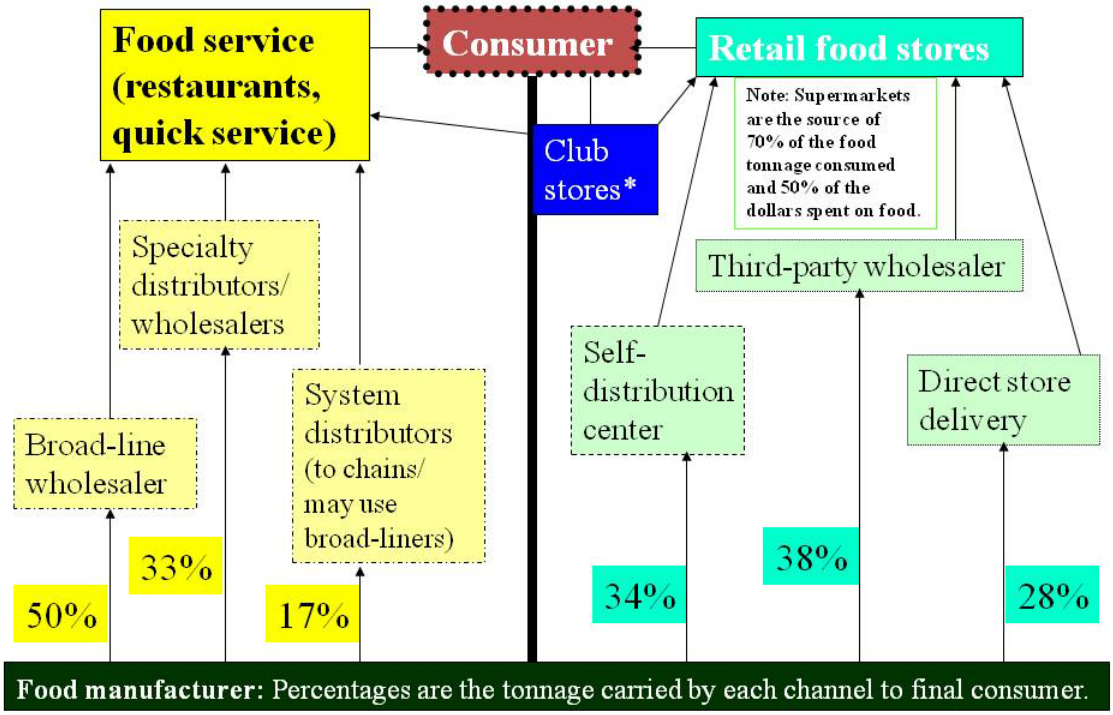
3) Dole distribution centers that received P227A from Marin or Springfield included those in **Redding, CA; Yuma, AZ; New York City; and Atlanta**.

4) Five secondary recalls occurred between September 15 and September 22 because Natural Selection had shipped spinach to companies that repackaged it. The companies that issued the recalls were Kenter Canyon Farms of **Sun Valley, CA**; River Ranch Fresh Foods of **Salinas, CA** (including Fresh N' Easy and Hy-Vee brands); Pacific Coast Fruit of **Portland, OR** (including Chef on the Run and Trader Joe's); Triple B Corp., doing business as S.T. Produce of **Seattle** (including Charlie's and T/H) and RLB Food Distributors of **West Caldwell, NJ** (including Balducci's and FreshPro). Natural Selection brands included 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.

Source: California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007

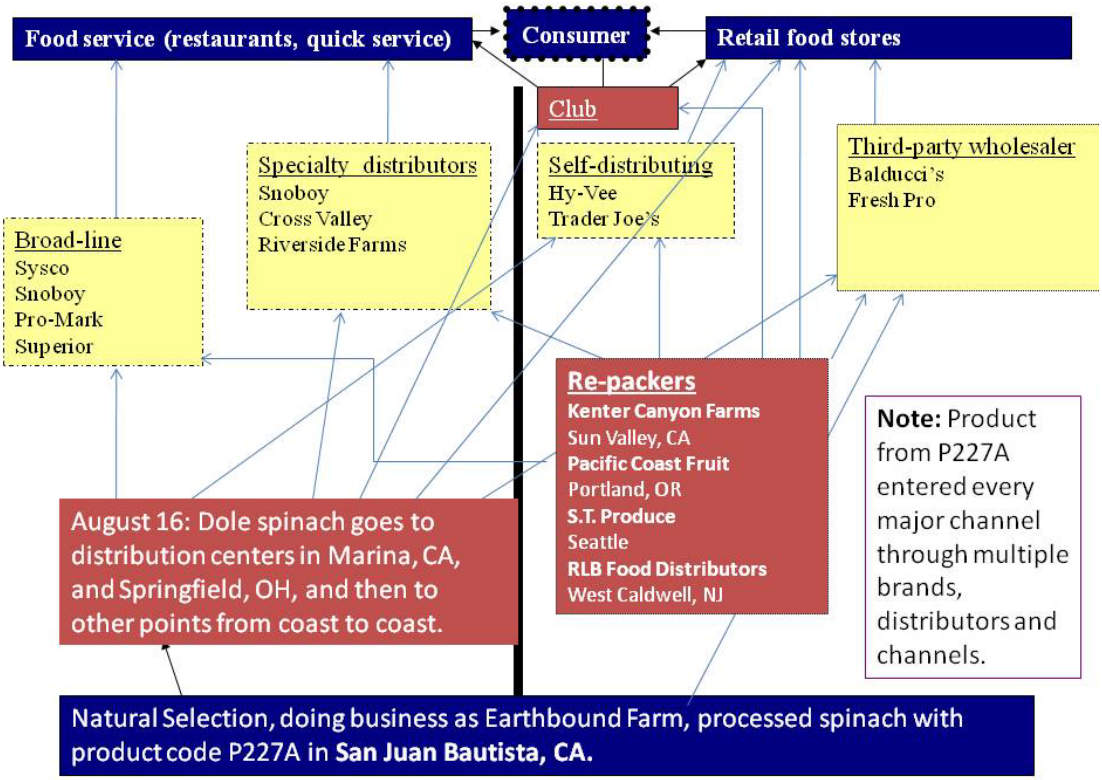
FIGURES 5 and 6: Food Supply Channel Maps

The following two maps show how food products in general go from manufacturer to consumer, as well as a closer look at the route of Natural Selection spinach:



*Club stores are included in retail and sell to consumers, small stores, and food service. Product tends to come direct from the manufacturer.

The spinach harvested by Mission Organics at the Paicines Ranch in Paicines, CA and packed by Natural Selection doing business as Earthbound Farm, processed spinach with product code P227A in San Juan Bautista, CA and shipped it to Dole distribution centers between noon August 15, 2006, and 5 a.m. August 16, 2006. From there, it followed a more complex route. Some of the spinach was also sent to four re-packers by Natural Selection, which in turn increased the number of products, brands, and resellers impacted.



A Closer Look at the Outbreak Timeline

On August 14, 2006: 1,002 pounds of spinach was harvested by grower Mission Organics at the Paicines Ranch.[30]

On August 15: Natural Selection Foods processed spinach that caused the *E. coli* O157:H7 outbreak. [31]

On August 16: Dole spinach went to distribution centers in Marina, CA and Springfield, OH, then was distributed coast to coast.

On August 27, Ruby Trautz, 81, of Bellevue, NE was hospitalized. On August 31, she died, the first fatality of the outbreak.[32]

On September 7, Marion Graff of Manitowoc, WI died. She would be identified as the second victim.[33]

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[30] USA Today, "Five Faces, Five Agonizing Deaths, One Year Later," September 21, 2007
[31] California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007
[32] USA Today, "Five Faces, Five Agonizing Deaths, One Year Later," September 21, 2007
[33] USA Today, "Five Faces, Five Agonizing Deaths, One Year Later," September 21, 2007

Three more deaths would occur in the next four months, though two of the deaths were not counted in the CDC's final list of victims. Bill Marler, a lawyer who represented the families of the two unofficial victims, said they were killed by the same *E. coli* O157:H7 strain and that their medical bills were paid by Natural Selection's insurer. Note: Natural Selection did not confirm this.[34]

On September 8, Wisconsin state health officials identified a cluster of *E. coli* O157:H7 illnesses and submitted the pulsed field gel electrophoresis (PFGE) patterns to the CDC via PulseNet to alert the entire network.[35] PulseNet confirmed that *E. coli* strains from infected patients in Wisconsin had matching PFGE patterns and identified the same patterns in other states.[36]

On September 12: the CDC confirmed that the *E. coli* O157:H7 strains from infected patients in Wisconsin had matching PFGE patterns.[37]

On September 13: Wisconsin and Oregon officials notified the CDC that most of the sickened individuals who had been interviewed reported eating fresh prepackaged spinach.[38] Oregon officials notified the California Department of Health Services (CDHS) about a cluster of *E. coli* O157:H7 illnesses that Oregon was investigating.[39] The CDC alerted the FDA of a multistate *E. coli* O157:H7 outbreak that appeared to be associated with the consumption of bagged spinach.[40] The FDA notified the CDHS of additional clusters in other states.[41]

What is PulseNet?

When a patient is diagnosed with *E. coli* O157:H7, a sample of the bacterial strain is sent to a participating PulseNet lab. PulseNet is a national network of public health laboratories that perform genetic fingerprinting on foodborne bacteria that result in human illness. Scientists use a process called pulsed-field gel electrophoresis (PFGE), a technique that subtypes bacteria. "After the bacterial strain is subtyped or 'DNA fingerprinted' at a lab, the fingerprint is then uploaded electronically to the national PulseNet database where it can be compared with other patterns in other states," says Christopher Braden, Chief of Outbreak Response and Surveillance at the CDC. "This gives us the capability to rapidly detect a cluster of infections with the same pattern occurring in multiple states. The strength of this system is its ability to identify patterns even if the affected people are geographically far apart."

— FDA Consumer

By September 14: the CDC had received reports from officials in eight states, reporting 50 cases of infection with *E. coli* O157:H7.Many of the individuals recalled eating fresh prepackaged spinach in the week before they became sick. Daily conference calls were instituted with state and

[34] USA Today, "Five Faces, Five Agonizing Deaths, One Year Later," September 21, 2007
[35] California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007
[36] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[37] California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007
[38] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[39] California Department of Health Services and U.S. Food and Drug Administration, "Addendum Report to 'Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach,'" May 7, 2007
[40] California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007
[41] California Department of Health Services and U.S. Food and Drug Administration, "Addendum Report to 'Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach,'" May 7, 2007

federal agencies. Early in the investigation, many processors appeared to be implicated. As investigations progressed, illness was most often associated with Dole brand Baby Spinach processed by Natural Selection Foods at a facility in San Juan Bautista, CA. The FDA's San Francisco District Office and the CDHS, working jointly as the California Food Emergency Response Team (CalFERT), initiated an investigation at Natural Selection.[42] *The FDA and the CDC issued a public alert, advising consumers not to eat bagged spinach* and subsequently expanded the alert to all fresh spinach. Never before had the FDA made such a sweeping announcement about a U.S. fruit or vegetable.[43] CNN broadcasted the warning. This was an unusual step by the FDA, but with a perishable food like fresh spinach, much of it was in people's homes already. It was up to individual consumers to recall it from their refrigerators and destroy it at home. A store/restaurant level recall would not be enough. Neither frozen nor canned spinach was implicated.[44]

Will Daniels, Vice President of Food Quality and Safety for Natural Selection, remembers first hearing from the state of California at 8 a.m. September 14, 2006. In his view, it was too early for the government agencies to be talking with the companies potentially involved because their information was incomplete.

> *"The situation was evolving quickly. We kept getting different production codes, many of which were not ultimately linked to the outbreak. This is why it appeared that our traceback was slow and scattered,"* he said in the fall of 2008*. With fears running high but no definitive code information to pinpoint the exact product involved, the company voluntarily "recalled everything" on September 15. "Because the government acted very quickly and as a result we acted very quickly, it may have been a little more damaging to the industry than necessary and a little more damaging to the public, who stopped eating spinach."*

Daniels said although the company had well-documented and well-practiced recall and incident management programs in place, the company stumbled in a couple of ways, including forgetting to use a sample recall letter it had in place and instead hurriedly putting together a recall letter from scratch.[45]

On September 15: Natural Selection initiated a recall of all the products that contained spinach in all 30 brands it packed with "best-if-used-by" dates of August 17 through October 1.[46]

Five more companies issued recalls between Sept. 15 and Sept. 22. The secondary recalls occurred because Natural Selections had shipped spinach to other companies that repackaged it. The companies that issued secondary recalls were RLB Food Distributors, of West Caldwell, NJ; River Ranch Fresh Foods of Salinas, CA; Kenter Canyon Farms of Sun Valley, CA; Triple B Corp., doing business as S.T. Produce of Seattle; and Pacific Coast Fruit of Portland, OR.[47]

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[42] California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007
[43] Calvin, Linda,(2007) "Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices," *Amber Waves* . Washington D.C., U.S. Department of Agriculture, Economic Research Service. June 2007 www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm
[44] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[45] Interview of Will Daniels, Natural Selection vice president of food quality and safety, October 20, 2008
[46] California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007
[47] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007

On September 16, the FDA expanded its warning and advised consumers not to eat any fresh spinach or products containing fresh spinach. The agency advised retailers and food service operators that they should not sell raw spinach or blends that might contain raw spinach. "We expanded the advisory when we learned that bagged spinach was sometimes sold in an unbagged form at the retail level," said Robert Brackett, the FDA director who went on to become Chief Science Officer of the Grocery Manufacturers Association.

> *"We were also concerned about fresh spinach products that could still be in consumers' refrigerators. At that point, the priority was to prevent further illnesses. We wanted to get the word out and get fresh spinach off the shelves while we conducted an investigation to narrow down the source. The number of illnesses was increasing daily, which was alarming. And the reach was nationwide. We also knew that there were a significant number of severe illnesses and hospitalizations."*[48]

On September 20, New Mexico's public health laboratory announced that it had isolated the outbreak's strain of *E. coli* O157:H7 from an open package of spinach that came from the refrigerator of a patient who had become ill. The package of spinach that tested positive was Dole Baby Spinach with a best-if-used-by date of August 30. Later, the strain implicated in the outbreak also was isolated from open packages of fresh spinach consumed by ill people in several other states.[49] In the end, the Dole product was identified as the only contaminated product. [50]

The FDA's advice not to eat fresh spinach remained in effect until September 22, when the agency advised the public that fresh spinach implicated in the outbreak was grown in California's Monterey, San Benito, and Santa Clara counties and that spinach grown elsewhere was not implicated in the outbreak and could be consumed.[51]

On September 28, as the CDC reported 187 persons infected from 26 states, Natural Selection offered to pay victims' medical costs.

> *"We know it's the right thing to do for these people affected by this outbreak,"*

said Charles Sweat, the company's Chief Operating Officer. The company also announced that it had introduced new safety measures, including regular testing for *E. coli* on produce arriving at Natural Selection plants.[52]

On September 29, the FDA announced that all spinach implicated in the outbreak traced back to Natural Selection Foods.[53] FDA announced that "spinach on the shelves is as safe as it was before the event." [54]

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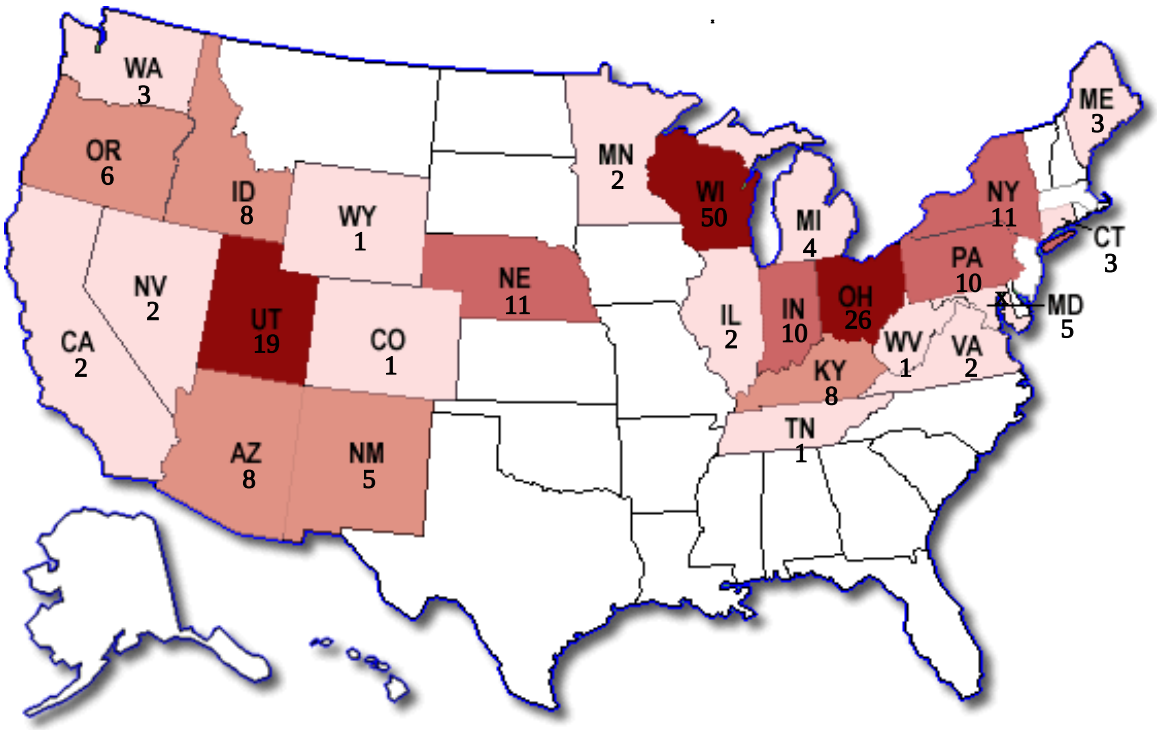
[48] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[49] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[50] Calvin, Linda,(2007) "Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices," *Amber Waves .* Washington D.C., U.S. Department of Agriculture, Economic Research Service. June 2007 www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm
[51] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[52] San Francisco Chronicle, Spinach Processor Responds to E. coli Outbreak," September 29, 2006
[53] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[54] Calvin, Linda,(2007) "Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices," *Waves .* Washington D.C., U.S. Department of Agriculture, Economic Research Service. June 2007 www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm

On October 12, the FDA and CalFERT announced that the strain of E. coli had been traced back to one of four implicated ranches, later known to be Mission Organics in Salinas, CA. However, the actual source of contamination was never definitively identified.[55]

As of January 2007, 205 confirmed illnesses and three deaths were attributed to the outbreak. Of the 103 case patients who were hospitalized, 31 developed hemolytic-uremic syndrome (HUS). The peak occurrence of onset of illness occurred between August 30 and September 1.[56] The 26 affected states are shown below. In addition, Canada had one confirmed case in the Province of Ontario.[57]

In April 2007, the attorney for the families of three women who died, two of whom had not been included in the official death toll, said that Natural Selection, Mission Organics and Dole Food had agreed in March 2007 to confidential settlements in the deaths of Ruby Trautz, 81, of Bellevue, NE; Betty Howard, 83, of Richland, WA; and June Dunning, 86, of Hagerstown, MD.[58]

FIGURE 7: *E. coli* O157:H7 Number of Illnesses by State



Source: CDC

[55] California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007
[56] California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007
[57] FDA Consumer, "Nationwide E. coli O157:H7 Outbreak: Questions & Answers," November-December 2006
[58] Los Angeles Times, "Lawsuits over Three E. coli Deaths Settled," April 23, 2007

How and Where Was the Product Contaminated?

No obvious sources for introduction of *E. coli* O157:H7 were found at the processing facility, though conditions were observed that might have contributed to its spread, if the *E. coli* O157:H7 arrived on incoming spinach. The final state and federal report on the outbreak cited inconsistencies between the company's sanitation schedule and actual frequency of cleaning and sanitation of certain areas, as well as incomplete records regarding the practices.[59]

The investigation into how the spinach might have become contaminated included sample collection in facilities and a review of animal management practices, processing practices, and water use. The field investigation discovered the same strain of *E. coli* O157:H7 involved in the illnesses in environmental samples collected at the Paicines Ranch that supplied spinach to Natural Selection.[60] A PFGE pattern indistinguishable from the outbreak strain was identified in river water, cattle feces and wild pig feces in the cattle pasture adjacent to spinach fields. However, the final report on the outbreak said, "No definitive determination could be made regarding how the *E. coli* O157:H7 pathogens contaminated spinach in this outbreak."[61]

Fencing around the cow pastures nearby appeared to keep cows from going into the spinach fields. But Gerald Wiscomb, an expert disease biologist on the team from the USDA's Wildlife Services, observed that pigs went into the crop fields on the ranch. "There are many possibilities," said Erica Pomeroy, an investigator in the San Francisco District of the FDA's Office of Regulatory Affairs. "It could be that the pigs rooted around the cow feces, contaminating themselves, and then later defecated in the spinach fields." Another possibility is that surface contamination from pig and cow feces in the pasture areas got into the ground water.[62]

The Impact of the Recall

Natural Selection's sales level went down 30 percent after the outbreak, said Will Daniels, Vice President, but had for the most part recovered within six months. Today sales are back where they were before the outbreak. "I would not say that's typical for the industry," he said.[63] The past two years have been tough for River Ranch, especially the six months after the outbreak, said Barry Eisenberg, Vice President. He said it took a year for spinach sales to get back to 85 percent of where they were and that 5 percent to 10 percent of spinach sales hadn't returned two years later, adding, "Some stores won't even sell spinach."[64]

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[59] California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007
[60] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[61] California Department of Health Services and U.S. Food and Drug Administration, "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach," March 23, 2007
[62] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[63] Interview of Will Daniels, Natural Selection vice president of food quality and safety, October 20, 2008
[64] Interview of Barry Eisenberg, River Ranch vice president of technical services, October 29, 2008

Scanner data from A.C. Nielsen shows that overall sales of fresh bagged spinach fell sharply after the recall and did not recover until January 2008 (see charts, next two pages). Unit sales of fresh bagged spinach fell by more than 70 percent, to 1.4 million units, between the four periods ending September 9, 2006, and October 7, 2006. Over the same period in 2005, unit sales increased by 7 percent, from 5.3 million units to 5.7 million units. Because of consumer promotions and packaging changes, the "mix" of units can change.

Dollar sales over the period in 2006 fell from $14.3 million to $3.7 million. Over the same period in 2005, dollar sales increased from $13.0 million to $13.6 million. In the six months following the recall (August 24, 2006, and February 24, 2007) the value of bagged spinach sales fell 43 percent and bagged salad with spinach fell 42 percent. Bagged salad without spinach was still down 8 percent.[65]

At the end of 2007, 15 months after the recall, sales of bagged spinach were not back to 2005 levels. It is not clear how much of that was due to a lack of demand and how much was due to the fact that producers also cut back on spinach acreage in the U.S. by 18 percent between 2005 and 2007.[66]

Sales in both units and dollars did not return to pre-recall levels until the end of January 2008.

What is Nielsen Data?

The Nielsen Company was established in the United States in 1923 by Arthur C. Nielsen, Sr. Perhaps best known worldwide for television audience measurement, the company is the leading supplier of retail point-of-sale (POS) check-out scanner data.

This data is considered to be one of the best sources for objective information on sales and competitive performance. Nielsen data provides a company with a window to see its sales relative to the sales in the total category at the same point in time. Absent Nielsen data, a company would know only its own sales for the period. A manufacturer of consumer packaged goods (CPG) would only know when it shipped the product, not when the product was finally sold to the consumer.

The Nielsen data does not include data from Wal-Mart, which does not make its data available to Nielsen.

[65] Calvin, Linda,(2007) "Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices," *Amber Waves*. Washington D.C., U.S. Department of Agriculture, Economic Research Service. June 2007 www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm

[66] Calvin, Linda, Helen Jensen and Jing Liang, (2009) "The Economics of Food Safety: The 2006 Foodborne Illness Outbreak Linked to Spinach" Chapter 22 in Microbial Safety of Fresh Produce, Ed. by Xuetong Fan, Brendan A. Niemira, Christopher J. Doona, Florence E. Feeherry and Robert Gravani.

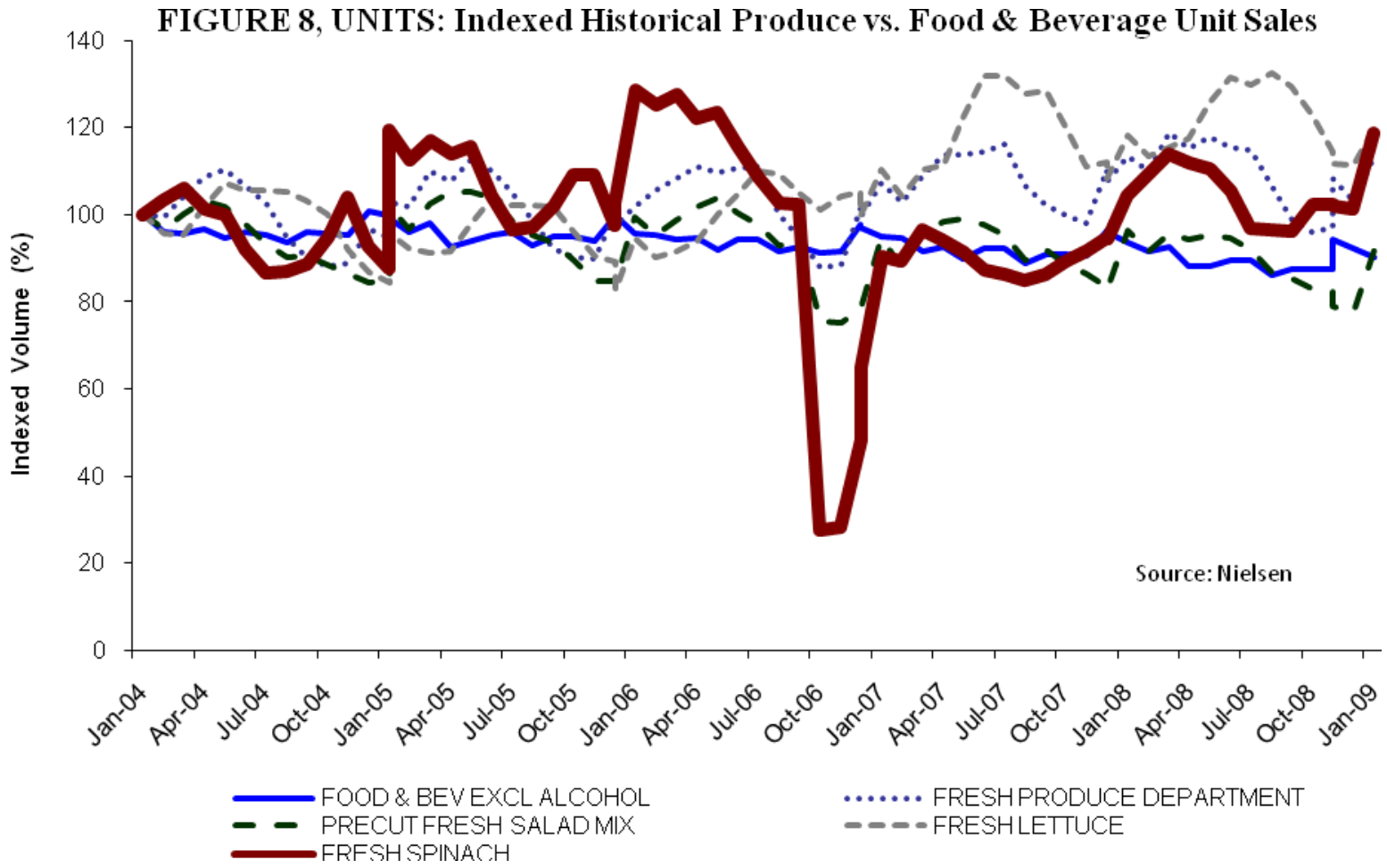
FIGURE 8, UNITS: Indexed Historical Produce vs. Food & Beverage Unit Sales
Indexed Volume (%)
140
120
100
80
60
40
20
0
Jan-04
Apr-04
Jul-04
Oct-04
Jan-05
Apr-05
Jul-05
Oct-05
Jan-06
Apr-06
Jul-06
Oct-06
Jan-07
Apr-07
Jul-07
Oct-07
Jan-08
Apr-08
Jul-08
Oct-08
Jan-09
Source: Nielsen
FOOD & BEV EXCL ALCOHOL
FRESH PRODUCE DEPARTMENT
PRECUT FRESH SALAD MIX
FRESH LETTUCE
FRESH SPINACH

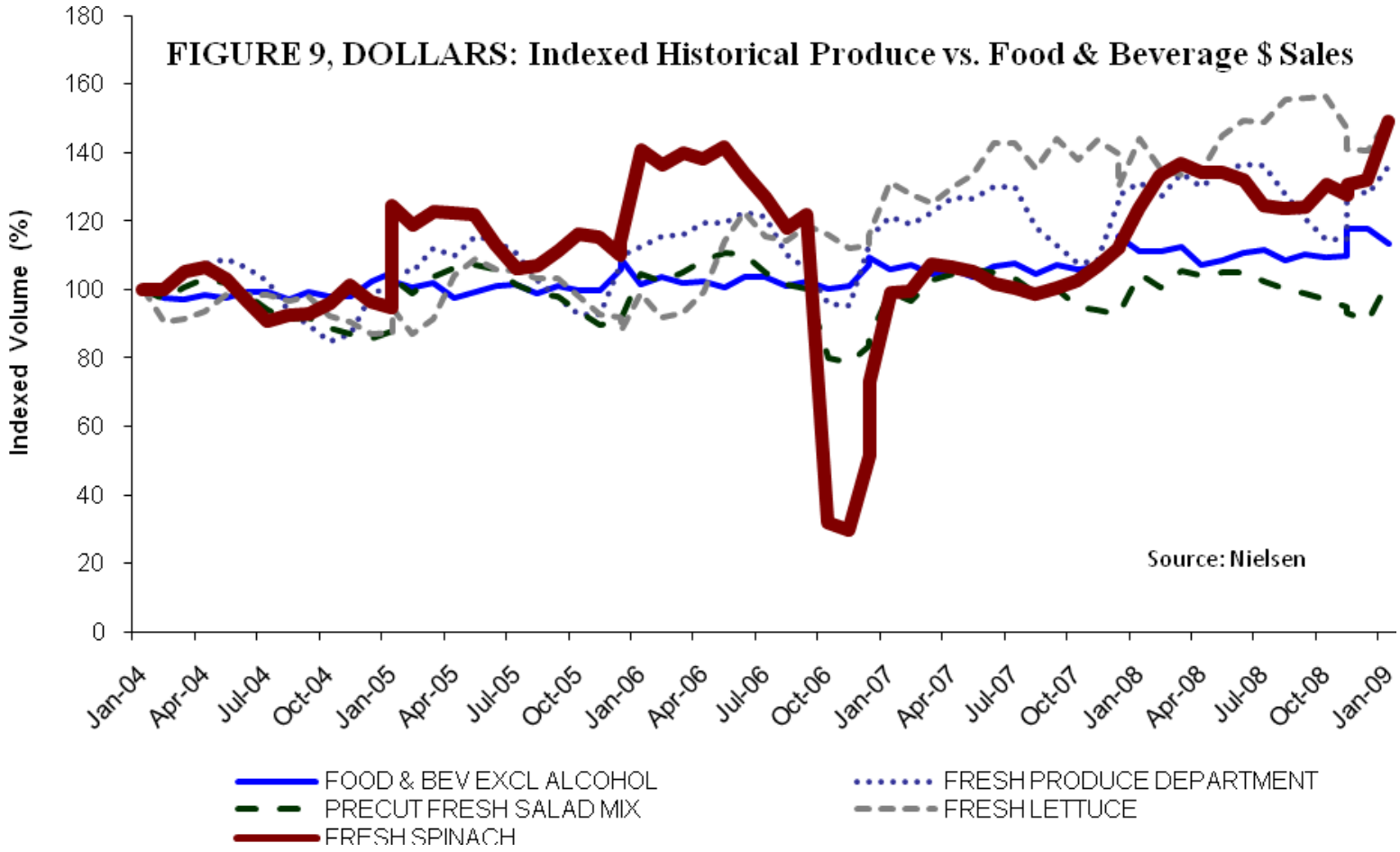
FIGURE 9, DOLLARS: Indexed Historical Produce vs. Food & Beverage $ Sales
Indexed Volume (%)
180
160
140
120
100
80
60
40
20
0
Jan-04
Apr-04
Jul-04
Oct-04
Jan-05
Apr-05
Jul-05
Oct-05
Jan-06
Apr-06
Jul-06
Oct-06
Jan-07
Apr-07
Jul-07
Oct-07
Jan-08
Apr-08
Jul-08
Oct-08
Jan-09
Source: Nielsen
FOOD & BEV EXCL ALCOHOL
FRESH PRODUCE DEPARTMENT
PRECUT FRESH SALAD MIX
FRESH LETTUCE
FRESH SPINACH

Produce-Related Outbreaks a Continuing Problem

Since 1996, there have been 24 outbreaks involving leafy greens, most traced to California. Many were traced to the Salinas Valley. Experts aren't sure why many of these outbreaks are linked to the Salinas Valley.[67]

The FDA instituted a Produce Safety Action Plan in 2004. The plan addressed microbial food safety hazards and good agricultural practices (GAPs) and good management practices (GMPs) common to growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or raw form. The plan contained four objectives: 1) preventing contamination of fresh produce with pathogens; 2) minimizing the public health impact when contamination occurs; 3) improving communications with producers, preparers, and consumers; and 4) facilitating and supporting relevant research.[68]

In 2004 and 2005, the FDA expressed its concerns with continuing outbreaks and its expectations for industry to improve produce safety. A February 2004 letter encouraged the lettuce and tomato industries to review practices in light of the FDA's GAPs and GMPs guidance. A November 2005 letter reiterated this concern and focused on fresh-cut lettuce and other leafy greens.[69]

TABLE 2: Foodborne Illness Outbreaks Attributed to Produce, 1996-2006

Commodity	Outbreaks
Leafy greens	
Lettuce	14
Mixed lettuce	1
Romaine lettuce	4
Spinach	2
Cabbage	1
Basil or mesclun lettuce mix	2
Tomatoes	12
Melons	
Cantaloupe	7
Other melons	4
Raspberries and other berries	6
Various others	16
Total	**71**

Source: FDA

In March 2006, the agency released draft guidance for the fresh-cut produce industry. The Lettuce Safety Initiative, developed in August 2006, supported the produce safety plan and covered lettuce and other leafy greens, including spinach. The initiative's key objectives included: 1) assessing industry approaches and stimulating efforts to improve lettuce safety; 2) identifying industry practices that potentially lead to contamination and developing policy or guidance and identifying research to minimize future outbreaks; 3) taking targeted regulatory action using a risk-based approach toward areas most likely to be the source of contamination; and 4) alerting consumers early and responding rapidly in the event of an outbreak.[70]

Charles Sweat, Chief Operating Officer of Natural Selection, said after the 2006 *E. coli* outbreak that the company would require a number of measures be taken by growers that supply their company with fresh-cut produce. These measures included working with growers from seed to

[67] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[68] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[69] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[70] FDA Consumer, "The FDA: Fresh Leafy Greens Grown in the United States Are Safe," November-December 2006

harvest, inspecting the seed, irrigation water, soil, plant tissues, and wildlife. The company also indicated that sanitation protocols for farm equipment and packaging supplies would be enhanced and monitored, and that a "firewall" would be set up to test all the freshly harvested greens before they enter the production stream.[71]

Eisenberg, Vice President at River Ranch, said the 2006 *E. coli* outbreak led to a complete reevaluation of his company's food safety procedures. "It made everyone go back, review and make sure we weren't missing something," he said. "Within four months, most people were acting on a lot of recommendations being made." Staffing in the field increased. Training and education of growers intensified and became more focused. Irrigation water monitoring has increased. Composting processes must be certified, with verification of no pathogenic material. Buffer zones are strictly enforced. Fields with animal activity are more closely scrutinized, and acres are taken out of production if need be. If an area of risk is found, samples are pulled and tested. Fields are monitored one to four days before harvest. "The growers who we associate with are only those who take food safety seriously," he said.[72]

In 2007, California's leading leafy greens producers formed the California Leafy Green Products Handler Marketing Agreement (LGMA), a voluntary self-regulatory organization organized as a Marketing Agreement under the supervision of the California Department of Food and Agriculture. Members represent more than 99 percent of the volume of the state's leafy greens and include both Natural Selection and River Ranch. Membership requires verification of compliance with accepted food safety practices through mandatory government audits. The food safety practices were developed by university and industry scientists, food safety experts and farmers, shippers, and processors.[73] A charge of approximately 2 cents per 50 pounds of product supports an inspection program to ensure compliance with traceback standards.[74] In the fall of 2009, the USDA conducted hearings on whether a national marketing agreement should be adopted for leafy greens.[75]

Daniels, Vice President at Natural Selection, said in the fall of 2008 that he was

> *"in a way, almost glad" that the final report on the 2006 E. coli outbreak did not definitively name a source of the contamination because it prompted the company to look at all potential risks and develop robust plans to mitigate every risk, rather than focusing on one identified problem.*[76]

Consumer activist groups continue to push for mandatory federal rules.[77]

Eisenberg said,

> *"We want to be regulated. We believe regulation is what is needed.*

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[71] FDA Consumer, "How the FDA Works to Keep Produce Safe," March-April 2007
[72] Interview of Barry Eisenberg, River Ranch vice president of technical services, October 29, 2008
[73] LGMA, www.caleafygreens.ca.gov
[74] Calvin, Linda,(2007) "Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices," *Amber Waves* . Washington D.C., U.S. Department of Agriculture, Economic Research Service. June 2007 www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm
[75] USDA, "USDA Sets Hearing for Proposed National Marketing Agreement for Leafy Green Vegetables," September 2, 2009
[76] Interview of Will Daniels, Natural Selection vice president of food quality and safety, October 20, 2008
[77] Los Angeles Times, "Tainted Spinach Tied to Cattle Ranch," March 24, 2007

We don't believe we can build consumer confidence without regulation. We've been looking to FDA to take some leadership."[78]

In April 2007, Fresh Express, a large bagged salad company, spent $2 million to support scientific research on *E. coli* 0157:H7 in leafy greens. Scientists from the FDA, the CDC, and the California Department of Health Services advised on the project. The Center for Produce Safety was established at the University of California-Davis and is supported by more than $5 million from the Produce Marketing Agreement. [79]

GAO Critical of FDA

Major food recalls spur regulatory debates and calls for greater regulation and oversight. The Government Accountability Office (GAO) has regularly criticized the FDA in the past few years, saying a number of improvements could be made in the FDA's operation. The FDA itself acknowledges many shortcomings. The agencies clearly differ in their opinions of whether the FDA is adequately addressing these issues.

In November 2007, a report by the Subcommittee on Science and Technology of the Science Board, which is the advisory board to the FDA commissioner, concluded that "science at the FDA is in a precarious position." The report's major findings were: 1) the FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak; 2) the FDA cannot fulfill its mission because its scientific workforce does not have sufficient capacity and capability; and 3) The FDA cannot fulfill its mission because its information technology infrastructure is inadequate. The report concluded: "In contrast to previous reviews that warned crises would arise if funding issues were not addressed, recent events and our findings indicate that some of those crises are now realities and American lives are at risk."[80]

Also in November 2007, the FDA released its Food Protection Plan, a set of integrated strategies that focus on risks over a product's life cycle from production to consumption. The plan targets resources to achieve maximum risk reduction, addresses both unintentional and deliberate contamination, and uses science and modern technology systems. As part of the plan, the FDA emphasized that it "cannot take some key actions without new legislative authority," including allowing additional preventive controls, strengthening certification procedures, and empowering the FDA to issue a mandatory recall of food products when voluntary recalls are not effective.[81]

In January 2008, the GAO said the Food Protection Plan proposed "positive first steps intended to enhance its oversight of food safety." The GAO noted, however, the FDA needed to provide more specific information about its strategies and the resources needed to implement the plan.[82]

In February 2008, at the request of several members of the U.S. House of Representatives, the FDA Science Board's Subcommittee on Science and Technology estimated the resources

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[78] Interview of Barry Eisenberg, River Ranch vice president of technical services, October 29, 2008
[79] Calvin, Linda,(2007) "Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices," *Amber Waves .* Washington D.C., U.S. Department of Agriculture, Economic Research Service. June 2007 www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm

[80] FDA Science Board, "FDA Science and Mission at Risk," November 2007
[81] FDA, "Food Protection Plan," November 2007
[82] GAO, "FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical," January 29, 2008

required to address scientific shortcomings at the FDA. The subcommittee recommended that the FDA's appropriated (non-user fee) budget be increased by $375 million in fiscal 2009, increased by an additional $450 million in fiscal 2010 and increased by an additional $460 million in fiscal years 2011, 2012 and 2013.[83]

The GAO reiterated its position on the Food Protection Plan in June 2008, noting that while the FDA planned to spend about $90 million over fiscal years 2008 and 2009 to implement several key actions, it remained unclear how much funding the FDA would need to implement the entire plan. The GAO also noted that of the 34 food safety-related recommendations it had made to the FDA since 2004, the FDA had implemented seven.[84]

In September 2008, the GAO issued a report titled, "Improvements Needed in FDA Oversight of Fresh Produce." The GAO recommended, among other things, the FDA update its guidance on good agricultural practices (GAPs) and its regulations on current good manufacturing practices (GMPs) for food and seek explicit authority from Congress to adopt preventive controls for high-risk foods and authority for enhanced access to records. The FDA agreed with most of the GAO's recommendations, but believed it had sought authority from Congress. The GAO said it did not view the FDA's actions as seeking authority because the FDA "has not drafted legislative language or formally submitted a legislative proposal to the Congress, nor has it worked directly with the Congress to help initiate these authorities.[85]

Every food contamination crisis pushes the discussion. **In March 2009,** following a nationwide *Salmonella* outbreak caused by contaminated peanuts, several U.S. senators introduced the FDA Food Safety Modernization Act of 2009. "This bill will help give us the tools and authority for better inspections and a more responsive recall system," said Sen. Amy Klobuchar of Minnesota. Many aspects of the bill echoed those of the FDA's Food Protection Plan.[86]

Agroterrorism: What if Contamination Were Intentional?

"We have been fortunate so far — we have not faced any direct attacks to our food supply,"
FBI Director Robert Mueller, below, told the first International Symposium on Agroterrorism in May 2005. "… But the absence of any direct attack on our food supply does not minimize the threat. We know that members of Al Qaeda have studied our agricultural industry."[87]

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[83] FDA Science Board, "FDA Science and Mission at Risk: Estimated Resources Required for Implementation," February 25, 2008
[84] GAO, "FDA Has Provided Few Details on the Resources and Strategies Needed to Implement Its Food Protection Plan," June 12, 2008
[85] GAO, "Improvements Needed in FDA Oversight of Fresh Produce," September 2008
[86] U.S. Sen. Amy Klobuchar news release, "Klobuchar Introduces Bill to Reform Food Safety System," March 3, 2009
[87] FBI, prepared text of speech by FBI Director Robert Mueller, May 5, 2005 www.fbi.gov/pressrel/speeches/mueller050505.htm. More of Mueller's comments: "One of the ways we are working together is through the Agricultural Intelligence Group. Members of this group — including the FBI, the CIA, the USDA, the FDA, the Department of Homeland Security, and the military — meet regularly to exchange information and ideas about food security, and to discuss ways in which we can best utilize our combined skills, technology, and resources. Another way we are working together is through various Scientific Working Groups, or 'Swigs.' Our FBI scientists are working with their counterparts around the country. One group, which includes scientists from the CDC, key laboratories around the

On October 4, 2006, the U.S. Attorney's Office for the Northern District of California announced that agents of the FBI and the FDA Office of Criminal Investigations executed two search warrants on Natural Selection Foods in San Juan Bautista, CA and Growers Express in Salinas, CA in connection with the *E. coli* outbreak. United States Attorney Kevin Ryan stated, "I want to reassure the public that there is no indication in this investigation that leaf spinach was deliberately or intentionally contaminated. We are investigating allegations that certain spinach growers and distributors may not have taken all necessary or appropriate steps to ensure that their spinach was safe before it was placed into interstate commerce. Moreover, the investigation has not revealed any evidence of a new or continuing threat to public health in connection with the matters under investigation."[88] The U.S. Attorney's Office announced on June 21, 2007, that it had closed the investigation after determining that federal criminal charges were not warranted.[89]

Nonetheless, the FBI called the *E. coli* outbreak "a stark reminder of how important it is to protect the nation's food supply." "Our goal is to protect and prevent," said FBI Special Agent Craig Watz, who helped organize the second International Symposium of Agroterrorism in September 2006. "If agroterrorism is to occur, how do we best contain it? How do we best respond to it?" In the event of an attack, the FBI would focus on the criminal investigation while the FDA and USDA would center their attention on containing the public health risks. The FBI would collect the suspected hazardous material and send it to a network of labs with standardized procedures for identifying biological or chemical pathogens—a process that 10 years ago took days, but today takes hours. If the samples were positive, the FBI would establish a Joint Operations Center with representatives from Homeland Security, the Department of Defense, HHS, EPA, FDA, and FEMA, along with local law enforcement, public health officials, and scientists.[90]

A Similar, More Recent Incident: Tomatoes and Peppers Recall of 2008

In the spring and summer of 2008, a similar incident threatened consumers, the food industry, and government. An outbreak of *Salmonella* Saintpaul ultimately sickened more than 1,400 people, hospitalized almost 300 and possibly contributed to two deaths. The outbreak began in late April, and most people were sickened in May and June. At first, certain types of raw tomatoes seemed to be the culprit, and later raw jalapeno peppers and raw Serrano peppers were blamed.[91] The table below illustrates why the ability to trace

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country, the CIA, and the Department of Homeland Security, analyzes animal and plant pathogens — down to the DNA level — to distinguish between pathogens that occur in nature and those that are intentionally spread. This distinction is important. If a car bomb explodes outside of a building, we know the attack was intentional. But if a cow contracts Foot and Mouth Disease or a soybean plant exhibits rust, it can be difficult, if not impossible, to determine whether the attack was intentional or occurred naturally. But we are not limiting our partnerships to the federal level. We are reaching out to the people on the front lines — our farmers, cattle ranchers, food producers, and distributors. In 2003, with the help of our Albuquerque Field Office, we started a program called AgriGard. Through a secure web portal, members of the agricultural community are sharing information with each other, and with scientists, state and local law enforcement, and the FBI. Members can pose questions and alert the FBI to any suspicious or unusual activity. This program is a win-win for everyone involved."

[88] The Food Institute Report, "Search Warrants Issued over Spinach Outbreak," October 9, 2006

[89] U.S. Federal News, June 21, 2007

[90] FBI, "Protecting Against Terror: FBI Convenes Agroterrorism Summit," September 25, 2006 www.fbi.gov/page2/september06/agroterror092506.htm

[91] CDC, "Outbreak of Salmonella Serotype Saintpaul Infections Associated with Multiple Raw Produce Items — United States, 2008" MMWR Weekly, August 29, 2008

the illness to a particular food is more difficult when the pieces of food are commingled and mixed and matched along the supply chain.

TABLE 3: Tomatoes and Peppers – Commingling Packaging in Distribution

	Bagged spinach	Tomatoes and peppers
Field	• Field and farmer recorded	• Case packed for shipping field and farmer recorded
Packaging near the field	• Consumer packed with UPC OR bulk packed for further packaging.	• Cases often open and resorted by size and ripeness. Cases repacked – farmers and fields and packing house commingled.
Packaging near the consumer	• Sealed consumer pack with original date and packing lot information.	• Resorted for retail distribution. Damaged product discarded. Cases repacked – farmers and fields and packing houses commingled.

On June 3, 2008, the FDA alerted consumers in New Mexico and Texas that a *Salmonella* outbreak appeared to be linked to consumption of certain types of raw red tomatoes and products containing raw red tomatoes.[92] **On June 7,** the FDA expanded the warning, recommending that consumers nationwide not eat certain raw red plum, red Roma, and red round tomatoes unless grown and harvested in certain states and countries deemed to be safe.[93] In a little more than a month, the FDA held nine media briefings on the *Salmonella* outbreak. **On July 17,** the FDA updated its warning to consumers, saying that fresh tomatoes available in the United States were *not associated* with the outbreak and removed its June 7 warning against eating certain types of red raw tomatoes. The FDA said it continued to follow evidence suggesting that raw jalapeno and raw Serrano peppers may have been linked to illnesses in the outbreak.[94] **On July 21,** Agricola Zarigoza Inc. of McAllen, TX, recalled jalapeno peppers distributed since June 30 because they had the potential to be contaminated with *Salmonella*. FDA sampling had revealed that the peppers were contaminated with the same strain of *Salmonella* Saintpaul responsible for the

[92] FDA, "FDA Warns Consumers in New Mexico and Texas Not to Eat Certain Types of Raw Red Tomatoes," June 3, 2008
[93] FDA, "FDA Warns Consumers Nationwide Not to Eat Certain Types of Raw Red Tomatoes," June 7, 2008
[94] FDA, "FDA Lifts Warning About Eating Certain Types of Tomatoes," July 17, 2008

outbreak.[95] **On July 25,** the FDA said that jalapeno and Serrano peppers grown in the United States were not connected with the outbreak, but continued to advise consumers to avoid raw jalapeno peppers and food containing them if the peppers had been grown, harvested, or packed in Mexico. The FDA also said it had determined that the Agricola Zaragoza produce distribution center was not the original source of contamination.[96] **On July 30,** the FDA extended its consumer warning, advising consumers to avoid raw Serrano peppers from Mexico in addition to raw jalapeno peppers from Mexico.[97] **A month later,** the CDC declared the threat over, and the FDA lifted its advice to consumers to avoid eating the peppers grown, harvested, or packed in Mexico.[98]

Ultimately, the CDC said: "Preliminary epidemiologic and microbiologic results to date support the conclusion that jalapeno peppers were a major vehicle by which the pathogen was transmitted and Serrano peppers also were a vehicle; tomatoes possibly were a vehicle, particularly early in the outbreak. Contamination of produce items might have occurred on the farm or during processing or distribution; the mechanism of contamination has not been determined. These findings indicate that additional measures are needed to enhance food safety and reduce illnesses from produce that is consumed raw."[99]

The incident reinforced that raw produce, despite its many virtues, can transmit dangerous pathogens far and wide, that pathogens can be introduced at many different steps in the path from producer to consumer, and that it can be very difficult to trace the source of contamination. Additionally, when outbreaks occur and actions are quickly and necessarily taken in order to limit sickness, many innocents can be affected throughout the food industry.

Conclusions

Fresh produce is grown in an open environment, consumed within a short time frame, and packed under a wide variety of labels. It offers unique food safety challenges, according to Timothy L. Sellnow, a Professor of Communication at the University of Kentucky and a researcher for the National Center for Food Protection and Defense:

"The success or failure of risk and crisis communication where food recalls are involved depends on two factors: a) the rapid identification of the toxic agent and its source; and b) the prompt communication of crisis messages to relevant consumers. Fresh produce such as spinach poses a heightened risk due to the short time between harvest and consumption. Regardless of the industry's capacity for rapidly tracking the origin and delivery of fresh produce, any response to an accidental or intentional contamination is complicated by the fact that fresh produce is consumed in a relatively short time after harvest. Hence, any warning and recall process must be

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[95] FDA, "Agricola Zaragoza, Inc. Recalls Jalapeno Peppers Because of Possible Health Risk," July 21, 2008
[96] FDA, "U.S. Grown Jalapeno and Serrano Peppers Not Connected to Salmonella Saintpaul Outbreak," July 25, 2008
[97] FDA, "FDA Extends Consumer Warning on Serrano Peppers from Mexico," July 30, 2008
[98] CDC, "Outbreak of Salmonella Serotype Saintpaul Infections Associated with Multiple Raw Produce Items — United States, 2008" MMWR Weekly, August 29, 2008, and www.fda.gov/oc/opacom/hottopics/tomatoes.html#news
[99] CDC, "Outbreak of Salmonella Serotype Saintpaul Infections Associated with Multiple Raw Produce Items — United States, 2008" MMWR Weekly, August 29, 2008

enacted within days of shipment. Of course, portions of the product that is frozen or canned pose less urgency.

"Sadly, the short response time associated with fresh produce makes it a potentially appealing commodity type for bioterrorists. As this case study accurately notes, terrorist attacks on the food supply are a confirmed threat. An intentional attack on a widely distributed product such as spinach would cause extensive harm to consumers and likely cripple the industry financially. This economic impact would likely spread beyond a specific product to include fresh produce of many kinds. For example, initial assumptions that a *Salmonella* outbreak was associated with tomatoes had a devastating and lasting impact on tomato products that continued even after tomatoes were vindicated as the source of the outbreak. (Spokespersons for the tomato industry claim they collectively lost more than $100 million.) Thus, risk communication planning should include a dedication to the rapid identification of a contaminant, the immediate communication of warning messages, and a prolonged message campaign to provide the media and the general public with messages distinguishing the contaminated products from those that are safe. The compressed time factor associated with fresh produce makes such planning imperative."[100]

Donald W. Schaffner, an Extension Specialist in Food Science and Professor at Rutgers, said the fresh food supply is vulnerable to terrorism:

"While it's clear that this (spinach) was not an intentional event, this case study does point out the vulnerabilities of the fresh food supply to contamination by terrorist. The product is grown in the open, and the product receives minimal processing prior to consumption. As the case study points out, terrorists are apparently aware of the possibility of agroterrorism and the vulnerability of the produce system. Contamination of fresh produce appears to present far fewer problems to the terrorist compared to attacking the canned food industry, for example. This case study points out the need for vigilance by the industry as well as rapid response once a contamination event is detected."[101]

[100] Timothy L. Sellnow, personal communication, June 2009
[101] Donald W. Schaffner, personal communication, June 2009

Discussion Questions

The Natural Selections recall raises several important questions:

Knowing that the risk of contamination in fresh produce can only be minimized, not eliminated, what is the consumer role in food safety and defense? Short of cooking all produce, what steps might be necessary?

Given the relatively short shelf life of many fresh produce items and the longtime industry practice of reselling product in both bulk and packaged forms and packed under multiple brands by the same packer along the supply chain, do industry, government and the consumer have to accept more ambiguity in rapidly evolving produce recalls?

What unique challenges are created by the packing and repacking and then mixing by multiple companies to the information-flow and communications processes?

What are the costs and benefits of preventative food safety measures adopted by food producers/processors compared with taking the risk of having a major recall due to illness and death?

Glossary

CalFERT: The California Food Emergency Response Team consists of investigators and analysts from FDA San Francisco and Los Angeles district offices and California's Food and Drug office. The team was established in 2003 to rapidly respond to emergencies involving products the FDA regulates.

CDHS: California Department of Health Services. The department reorganized in July 2007. The reorganization established the California Department of Public Health (CDPH) and renamed the former CDHS to the Department of Health Care Services (DHCS).

Escherichia coli (abbreviated as *E. coli*) are a large and diverse group of bacteria. Although most strains of *E. coli* are harmless, others can make you sick. Some kinds of *E. coli* can cause diarrhea, while others cause urinary tract infections, respiratory illness and pneumonia, and other illnesses. Some kinds of *E. coli* cause disease by making a toxin called Shiga toxin. The most commonly identified STEC in North America is *E. coli* O157:H7.

GAPs: Good agricultural practices.

GMPs: Good manufacturing practices.

HUS: Hemolytic uremic syndrome is an infection caused by *E. coli* O157:H7 in which the red blood cells are destroyed and the kidneys fail.

LGMA: California Leafy Green Products Handler Marketing Agreement, instituted in 2007. Membership requires verification of compliance with accepted food safety practices through mandatory government audits.

Outbreak: The CDC defines an outbreak as two or more cases of the same disease related to a common exposure.

PFGE: Pulsed-field gel electrophoresis, a technique that subtypes bacteria.

PulseNet: PulseNet is a national network of public health laboratories that perform genetic fingerprinting on foodborne bacteria that result in human illness. After a bacterial strain is subtyped, it is uploaded electronically to the national PulseNet database. The network is able to identify patterns even if affected people are geographically far apart.

Traceback investigation: An attempt by companies or government agencies to work backward along the food chain to find a source of contamination.

Appendices

I. List of Recalled Products

(source: FDA, "Nationwide E. coli O157:H7 Outbreak: Questions & Answers" September 16, 2006, updated October 20, 2006 www.cfsan.fda.gov/~dms/spinacqa.html#brands)

Based on recall audits conducted by FDA, the agency recently determined that on September 15, 2006, Kenter Canyon Farms, Inc., of Sun Valley, California initiated a voluntary recall of re-packaged spinach. The recalled spinach was part of the nationwide recall of Natural Selection Foods. The product was packaged in 5 oz. clam shell plastic containers. The products recalled were: Kenter Canyon Farms Baby Spinach, Kenter Canyon Farms Mesclun, and Kenter Canyon Farms Spicy Mix. The recalled products were distributed only in Southern California. The "expiration date" located on the back of the package is September 20, 2006.

On 9/22/06, Pacific Coast Fruit Company of Portland, Oregon initiated a voluntary recall of its spinach salad products and pizza that may include spinach supplied by Natural Selections Foods, a California grower and processor. These products may be contaminated with E. coli O157:H7. Products recalled were distributed through various retail outlets in Alaska, Oregon, Washington and Idaho and include: Baby Spring Mix Salad Kit (4.6 lbs), Chef on the Run- Bacon Spinach Salad (9oz plus 2fl oz dressing), Chef on the Run-Spring Greens Salad (5oz plus 2fl oz dressing), Trader Joe's-Baby Spinach and Greens with Bleu Cheese, Candied Pecans and Cranberries with Raspberry Vinaigrette Dressing (10oz), Trader Joe's-Baby Greens and Spinach Salad with Wild Maine Blueberry Dressing (10oz), Mediterranean Veggie Blend Kit- 15lbs and My Brothers Pizza Spinach and Garlic- 15oz and 36oz. Salad products were distributed on "clam shells" and will have a "USE BY DATE" of on or before September 20, 2006. Pizza products were distributed on "round cardboard bottoms with a plastic over wrap" and will have a "USE BY DATE" of on or before September 23, 2006. Pacific Coast Fruit Company discontinued making all products with spinach supplied from California on September 14, 2006.

On 9/22/06 Triple B Corporation, doing business as, S.T. Produce of Seattle, Washington initiated a northwest states voluntary recall of certain salad products that may contain spinach 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, a California grower and processor, to S.T. Produce. This recall was initiated subsequent to an announcement by Natural Selections Foods of a nation-wide recall of all their products that contain spinach because they may be contaminated with E. coli 0157:H7. The recalled products were distributed in Washington, Oregon, Idaho and Montana to retail stores and delis. The salad products were sold in a hard plastic clamshell container with the "Use By" date located on the bottom of the container. The products being recalled include: 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 (5oz), and Caesar Bowtie Noodle Salad Kit with Grilled Chicken Breast (6.9lbs).

On 9/17/06, 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. 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.

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.

II. Federal Class I Food Recalls and Warnings in 2008

(source: FoodSHIELD, sponsored by the National Center for Food Protections and Defense www.foodshield.org)

January 2008

Olivier, Dip (*C. botulinum*)
Grassy Meadows, Cheese (*S. aureus*)
Shiloh Farms, Sesame Seeds (*Salmonella*)
Seoul Shik Poom, Inc., Fish (*C. botulinum*)
Inter-American Products, Bean Salad (*C. botulinum*)
New Era, beans (*C. botulinum*)
Rochester Meat Co., Beef (*E. coli O157:H7*)
Mark's Quality Meats, Inc., Beef (*E. coli O157:H7*)

February 2008

Walker's Food Products, Bean Salad (*C. botulinum*)
Hallmark/Westland, Beef (High Impact Class II Recall)
Nutri-Foods, Inc., Sesame Seeds (*Salmonella*)
Choyce Products, Tuna (*Salmonella*)
New Era, Canned Vegetables (*C. botulinum*)

March 2008

Dole Fresh Fruit Co., Cantaloupes (*Salmonella*)
Spokane Produce, Inc., Cantaloupes (*Salmonella*)
Chiquita, Cantaloupes (*Salmonella*)
JARD Marketing, Cantaloupes (*Salmonella*)
Bounty Fresh, Cantaloupes (*Salmonella*)
Fresh Express Foods, Cantaloupes (*Salmonella*)
Simply Fresh Fruit, Cantaloupes (*Salmonella*)
Tropifresh, Inc., Cantaloupes (*Salmonella*)
T.M. Kovacevich, Cantaloupes (*Salmonella*)
Central American Produce, Cantaloupes (*Salmonella*)

April 2008

Chang Farm, Soy Sprouts (*Listeria*)
Piney Ridge Dairy, Raw Milk (*Listeria*)
Malt-O-Meal, Cereal (*Salmonella*)
Taylor Fresh Foods, Cantaloupe (*Salmonella*)
Grand Supercenter, Croaker (*C. botulinum*)

May 2008

Fresca Italia Inc., Burrata (*L. monocytogenes*)
Orval Kent Foods, Macaroni Salad (*E. coli O157:H7*)
Supreme Cuts LLC., Corn (*L. monocytogenes*)
Cecina Los Amigos, Sausages (*Listeria*)
Sofia Chicharones Inc., Pork Crackling (*Salmonella*)
JSM Meat Holdings Co., Beef Products (*E. coli O157:H7*)
Sweetwater Valley Farm, Cheese (*Listeria*)
Palama Holdings, Ground Beef (*E. coli O157:H7*)
Gourmet Boutique, Meat and Poultry (*Listeria*)

June 2008
Nebraska Beef Ltd, Ground Beef (*E. coli O157:H7*)
Kroger Co., Ground Beef (*E. coli O157:H7*)
Fresca Italia, Inc., Cheese (*L. monocytogenes*)
Tipu's Tiger Chai Inc., Chai Tea (*C. botulinum*)
Gourmet Foods Inc., Chicken Products (*Listeria*)
Dutch's Meat Inc, Meat Products *(E. coli O157:H7*)
Tomatoes/Peppers (*Salmonella*)

July 2008
Consumer Warning: Serrano Peppers (*Salmonella*)
Vita Food Products, Inc., Salmon (*Listeria*)
Beef Packers Inc., Beef Products (*E. coli O157:H7*)
Agricola Zaragoza, Inc, Jalapeno Peppers (*Salmonella*)
Grande Produce Co., Peppers (*Salmonella*)
Lucky Green Trading Inc., Basil (*Salmonella*)
Salmolux Inc., Smoked Salmon (*Listeria*)

August 2008
Trans-Ocean Products, Inc., Salmon (*Listeria*)
Landshire, Inc., Sandwiches (*Listeria*)
Interior Alaska Fish Processors, Inc., Salmon (*Listeria*)
Home Made Brands Food, Tuna Salad (*Listeria*)
Renna's Meat Market, Beef (*E. coli O157:H7*)
Palama Holdings LLC, Pork (*Listeria*)
Nebraska Beef, Ltd., Beef (*E. coli O157:H7*)
S&S Foods LLC., Beef (*E. coli*)
DBC Inc., Chicken (*Listeria*)

September 2008
Food Evolution, Inc., Turkey Burrito (*Listeria*)
King Car Food Industrial Co., Coffee (Melamine)
QFCO, Inc., Candy (Melamine)
NY Fish Inc., Smoked Salmon (*Listeria*)
Sprouters Northwest, Inc., Alfalfa Sprouts (*Salmonella*)

October 2008
Everlasting Distributors Inc., Biscuits (Melamine)
Portland Shellfish Co. Inc, Lobster (*Listeria*)
The Hartz Mountain Corp., Rawhide Chips (*Salmonella*)
Lotte USA Inc., Cookies (Melamine)
Vermont Livestock, Ground Beef (*E. coli O157:H7*)
Hua Xia Food Trade USA, Inc. Milk Drink (Melamine)
Packers Provisions, Beef Trim (*E. coli O157:H7*)
Packers Provisions, Beef Trim (*E. coli O157:H7*)
USDA: ACS Meyners Ltd., Beef Trimmings (*E. coli*)
YS Trading Corp., Frozen Croaker (*C. botulinum*)

November 2008
Home Market Foods, Inc., Beef Sandwiches (*Listeria*)

Dutch Prime Foods, Inc., Ground Beef (*E. coli O157:H7*)
R.L. Zeigler Co., Inc., Hot Dog Products (*Listeria*)

December 2008
Home Fresh Sandwich Distributors, Inc., Burritos (*Listeria*)
T. Piekotowski, Sausage (*Listeria*)
DeNiro Cheese, Sausage (*Listeria*)
National Brands, Inc., Wafer Rolls (Melamine)
Dorsey Marketing Inc., Hot Cocoa (Melamine)
Michael and Charles LeBlanc Fisheries, Ltd., Fish (*C. botulinum*)
Cambrooke Foods, LLC, Imitation Cream Cheese (*Listeria*)
Rupari Food Services, Pork (Dioxin)
Interfood Shareholding Co., Biscuits (Melamine)
Walgreens, Chocolate (Melamine)

III. Major Foodborne Illness Events:
Deaths and Illnesses Caused by Food Contamination

(source: U.S. News and World Report, "Timeline: Deaths and Illnesses Caused by Food Contamination," May 20, 2007
health.usnews.com/usnews/health/articles/070520/28food.timeline.htm and CDC)

2009

November 2008-early 2009: *Salmonella*-tainted peanut products manufactured by the Peanut Corporation of America and used in many other products sickened hundreds of people in 45 states and might have contributed to nine deaths.

2008

April-August: *Salmonella* sickened 1,442 people in 43 states, the District of Columbia and Canada. The investigation showed that jalapeno peppers were a major source of contamination, that serrano peppers were also a source, and that tomatoes were possibly a source. The infection might have contributed to two deaths. The jalapeno peppers were traced back to distributors in the United States that received produce grown and packed in Mexico.

2007

August 2006–February 2007: *Salmonella*-tainted peanut butter from the Peter Pan and Great Value brands sickened hundreds of people in 44 states.

2006

November–December: 71 people became sick with *E. coli* after eating at Taco Bell restaurants in New Jersey, New York, Pennsylvania and Delaware. The fast-food chain initially blamed its green onion supply, though investigations by the CDC later suggested that lettuce was the source of the problem.

September–October: Prewashed, bagged spinach from Dole was contaminated with *E. coli*. At least 205 consumers fell ill; three died. Investigators traced the strain back to a field in California.

2002

Fall: Pilgrim's Pride recalled over 27 million pounds of frozen and prepared poultry products after *listeria* was found at one of its Pennsylvania processing plants. Eight people died, and 50 became seriously ill.

1998

The Malt-o-Meal cereal company recalled approximately 3 million pounds of its Toasty-O's cereal after the product was found to contain *salmonella*. Nearly 200 people, many of them children, got sick.

Hot dogs and lunch meats from Sara Lee became tainted with *listeria* following mechanical work at the manufacturing plant. At least 15 died, and six miscarriages were attributed to the outbreak. Eighty customers also became seriously ill.

1997

August: After 17 people in Colorado contracted *E. coli* from eating hamburgers, supplier Hudson Foods recalled 25 million pounds of frozen patties.

Spring: The CDC noticed something unusual: Hundreds of Michigan children and schoolteachers were diagnosed with hepatitis A. Investigators discovered that a contaminated shipment of

strawberries had been imported the previous year and mislabeled as domestic. The strawberries were used in frozen desserts and served with school lunches. Ultimately, over 9,000 students were vaccinated.

1996

Shipments of Guatemalan raspberries were contaminated with the intestinal parasite *cyclospora*. An estimated 1,500 in the U.S. and Canada became infected before the cause was found. Investigators blamed the problem on unhygienic growing conditions. In response, the U.S. halted importation of the Guatemalan fruit. The ban was partially lifted in 1999.

Mid-1990s

In the past decade, thousands have become sick with food-borne illnesses like *E. coli* and *salmonella* after eating raw sprouts. Over 22,000 illnesses and two deaths have been traced to these outbreaks. The FDA estimates that 20 percent of all produce-related illnesses are from sprouts and recommends that diners avoid eating the vegetable raw.

1993

January: Four children died and at least 700 became ill after eating hamburgers from Washington state Jack in the Box fast-food restaurants. The meat was tainted with *E. coli*, and the burgers had not been cooked to a high-enough temperature to kill the bacteria..

1985

In one of the first large-scale *listeria* outbreaks in the United States, shipments of Jalisco's Mexican-style soft cheese were found to contain the bacterium. Eighteen people died, and 30 infant deaths and stillbirths were connected to the contamination.

April: *Salmonella* in milk sickened thousands and killed at least three throughout the Midwest. Investigators cited improper pasteurization at the processing plant.

1984

In Oregon, members of a commune led by guru Bhagwan Shree Rajneesh tried to influence a local land-use vote by spreading *salmonella* to their neighbors. Members of the group produced the bacterium in a lab and poisoned food at 10 local restaurants. No one died, but 751 people became ill.

IV: Selected Readings on the *E. coli* Recall
These five news articles and news releases reflect coverage of the event.

From Roadside Stand to Produce Empire
Until E. coli Outbreak, Natural Selection Foods Was a Model of Farming Achievement.

Michael S. Rosenwald and Sonia Geis, Washington Post, September 22, 2006

Drew and Myra Goodman, the husband-and-wife produce team whose business is at the center of the E. coli spinach crisis in California's Salinas Valley, did not plan on becoming farmers.

They grew up in Manhattan. Drew's father was an art dealer. Myra's father was a jewelry manufacturer. They went to college in California -- Drew in Santa Cruz, Myra in Berkeley -- and stayed. The reason: a 2 1/2-acre raspberry farm in the back of a Carmel Valley home, an investment property of Myra's family where the couple was living in a guesthouse.

To pass some time before graduate school, they opened a roadside farm stand. They grew raspberries, and baby greens, which they sold to a local chef. What they had left over, they packed in plastic bags to eat during the week. When the chef left town, they decided to sell the packaged greens to grocery stores on consignment. Those little plastic bags, coupled with the rise of busy consumers trying to eat more healthfully, led the Goodmans to a $360 million-a-year produce business.

"They started farming totally on a whim," said Samuel Fromartz, who detailed their story in his book "Organic, Inc." "They hit the right product at the right time, and the thing took off."

Their company, Natural Selection Foods LLC, is one of the largest fresh produce companies in the nation, and it elbowed into conventional greens after becoming popular for organic produce. Now Natural Selection is the focus of an investigation into E. coli contamination of fresh spinach that has shaken the state's $258 million-a-year industry and kept the popular vegetable off dinner tables across the country.

Michael Pollan, who wrote about the family in a recent book, "The Omnivore's Dilemma," said, "The real vulnerability in the business model is that when you highly centralize the food supply . . . when there is a problem, the problem is going to get really big."

Natural Selection's plant compound in San Juan Bautista, Calif., sprawls across the equivalent of at least two city blocks, with beige and gray industrial buildings and warehouses two stories high, mobile office trailers and parking spaces behind high chicken-wire fencing. A row of sunflowers and a small grassy lawn are planted near the entrance, and low fields of leafy greens surround the plant on all sides. Long trucks rumble in and out. Workers wear hard hats or hairnets and heavy boots.

This week, television news vans equipped with satellite dishes have parked at the edge of a spinach field, just close enough to the plant to show the company's logo behind the reporters.

One recent afternoon, camera stands and light deflectors sprouted from the dirt where long rows of overripe spinach reached a road next to the plant for Natural Selection's leading brand, Earthbound Farm. Reporters in vans fixed their makeup and chatted on cellphones while they waited to stand in the field and give their reports.

The Goodmans have not commented on the outbreak. However, a company spokeswoman told the Associated Press: "We are very, very upset about this. What we do is produce food that we want to be healthy and safe for consumers, so this is a tragedy for us."

Natural Selection and Earthbound are noted both for their size and their contributions to research on organic farming, said Bob Scowcroft, executive director of the Organic Farming Research Foundation in Santa Cruz, which receives some financial support from Earthbound.

Of the more than 2,000 organic farms in California, most are small, sole-proprietor businesses, Scowcroft said. Earthbound Farm and another company, Grimmway Farms, are the only two that have turned organic farming into big business.

Earthbound Farm operates some of its own fields, and partners with processors, but for the most part, the company has grown by operating as an intermediary between individual farmers and supermarket chains, Scowcroft said.

"They have relationships with 170 other farms, some of them very large," he said. Those farms are all along the West Coast, with some in Mexico and Chile, so produce can be picked year-round. The company promises an array of produce in vast quantities to a big-box store or grocery chain, and then contracts out with small farmers to grow what it needs, when it needs it.

"The box stores and supermarket chains are sort of the tail wagging the dog here," Scowcroft said, adding that small farmers respect Earthbound Farm for helping them reach wider markets.

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

September 29, 2006

Food and Drug Administration - Press Releases - (Food and Drug Administration)

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. coliO157: 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 [degrees] F or below. All produce that is purchased pre-cut or peeled should be refrigerated to maintain both quality and safety.

Many precut, 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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FOR IMMEDIATE RELEASE, P06-152, September 29, 2006

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Tainted spinach tied to cattle ranch
The bacteria blamed for three deaths and many illnesses last year genetically match samples from the San Benito County site.

Marla Cone, Rong-Gong Lin II, Los Angeles Times, March 24, 2007

Contaminated spinach that sickened hundreds of people and prompted an unprecedented nationwide recall last fall came from a cattle ranch east of Salinas, according to a report by state and federal investigators released Friday.

The spinach was grown on a 50-acre field owned by Paicines Ranch, which raises about 2,000 head of grass-fed cattle in the San Benito County town of Paicines, according to the report by the California Department of Health Services and the U.S. Food and Drug Administration's San Francisco District.

The ranch leases a small amount of cropland to Salinas-based Mission Organics.

Twenty-six samples of feces, soil and surface water at the ranch matched the genetic strain of bacteria in bags of spinach that made people sick.

A Natural Selection Foods packaging plant in San Juan Bautista was the only processor involved, the report says.

Although the long-awaited findings of the joint federal and state investigation point to one California-grown crop and one processing plant, health officials stressed that pathogens in vegetables and fruits are a serious nationwide health problem. Outbreaks of potentially lethal illnesses linked to produce -- particularly leafy greens -- have been growing more frequent and larger in scope in recent years.

Three people, including a toddler, died in the spinach outbreak of last August and September, when 205 illnesses were reported in 26 states. The Centers for Disease Control and Prevention estimated that about 4,000 people were sickened by the spinach, taking into account that relatively few cases are typically reported.

The contamination probably occurred in the Mission Organics crop before harvest, but it might have spread further during bagging and processing at the Natural Selection plant, according to the investigators.

"No obvious sources for introduction of the pathogen were identified at the processing facility. However, a number of conditions were observed that may have provided opportunities for the spread of pathogens, if pathogens arrived on incoming spinach," the report says.

The same type of pathogen that caused the outbreak, E. coli O157:H7, was discovered in feces, river water and soil at three other spinach farms nearby, suggesting that the bacterium, which originates in cattle, is widespread in the greater Salinas Valley, where much of the nation's produce is grown.

However, the bacteria at those three farms did not genetically match the outbreak strain.

Water or wild pigs are the most likely sources of contamination at the Paicines Ranch, according to the report. E. coli O157:H7 was discovered in river water as well as feces from cattle and feral pigs on the ranch.

The San Benito River, which flows through the ranch and picks up E. coli from cattle manure, could have tainted the ranch's well water. The river water might have percolated into the groundwater tapped by the wells, the report says.

Also, the ranch has a large population of feral pigs that could have spread feces to the spinach. Fences on the ranch had holes and looked as though pigs had dug under them.

Brad Sullivan, an attorney for Mission Organics, said the report did not conclusively link the company with the E. coli, emphasizing that it was not found in the spinach field but on ranchland a mile away.

Sullivan stopped short of saying Mission Organics feels responsible for the outbreak, but said the company does feel "very concerned."

Sullivan said Mission Organics will not use its leased land in Paicines to grow more crops until the company and officials address the most likely sources of bacteria -- wildlife and water.

Bob Perkins, executive director of the Monterey County Farm Bureau, said "it appears none of the regulatory agencies nor the farmers can say, 'Aha, this is the cause, and if we fix this, this won't happen again.' "

Natural Selection Foods said in a statement that the investigation was "careful and thorough" even though most people hoped for "a more decisive conclusion" about the cause. The company said it would like to see national standards for produce.

"What is certain is that E. coli O157:H7 and other pathogens are present in the environment, and research and regulation are urgently needed," the company said.

Natural Selection said it has begun a more extensive testing program at its plants and in fields. "We believe our salads are safer than ever before," the company said.

The packaging plant did not have a valid state permit at the time of the outbreak because Natural Selection was leasing it and preparing to buy it from Pride of San Juan and had not yet obtained a permit under its name, the report says. No fines have been assessed.

State officials are working with Mission Organics and Natural Selection to ensure safe agricultural practices are followed.

"What relative roles each of these played, we don't know for sure," said Dr. Kevin Reilly, deputy director of prevention services at the state health department.

The spinach in the outbreak, sold under a Dole label, was grown in an organic way but was not labeled or certified organic.

Federal and state officials said their six-month investigation was the first time a pathogen was tracked from fork to field.

Dr. David Acheson, chief medical officer of the FDA's Center for Food Safety and Applied Nutrition, said it's critical for every farm and processor to follow national guidelines to minimize bacteria on produce.

"A relatively small plot can potentially be the source of a nationwide outbreak," he said, adding that more research is needed to "find out how these bugs get onto produce in the first place."

The FDA has asked produce growers and processors since 1998 to follow a long list of steps to minimize the danger of pathogens on fresh fruits and vegetables, including recommendations for water testing, worker hygiene, handling of manure and control of wild animals. Then, in 2004 and 2005, the FDA sent letters to growers of leafy greens expressing concern about outbreaks and again advising them to follow the guidelines. The guidelines, known as Good Agricultural Practices, are voluntary and no field inspections are conducted.

State Sen. Dean Florez (D-Shafter), who has introduced bills that would make the agricultural practices mandatory for growers of leafy greens, said the report "sounds like a broken record" and "is devoid of any action plan." He called it "shameful" that state regulators "have relegated themselves to the position of simple spectators to the most deadly E. coli outbreak emanating from California."

In the last decade, 72 bacterial and viral outbreaks have been caused by contamination of fruits and vegetables, led by leafy greens with 22 outbreaks, followed by tomatoes and melons.

The FDA is debating a new national strategy for produce that could remain voluntary or include some mandatory rules.

In the meantime, the California produce industry on April 1 plans to initiate a voluntary agreement that has been signed by handlers who account for 90% of the state's spinach. Those who sign the agreement must buy crops only from farmers who follow guidelines being developed by an industry board.

"The ultimate goal is to move this to a mandatory program for all growers and all suppliers," said Hank Giclas of the Western Growers Assn., which developed the agreement.

Consumer activist groups are pushing for mandatory federal rules.

Voluntary programs "utterly failed," said Elisa Odabashian of the Consumers Union, a national activist group. "Consumers are really sitting ducks. They need government intervention."

Schwarzenegger administration officials say the industry-led, voluntary approach is the quickest solution.

The new agreement "will reduce risk substantially," said Dr. Jeff Farrar, chief of the state health department's food and drug branch, although he warned that "we will not achieve zero risk in the near future for this commodity."

How the FDA Works to Keep Produce Safe

FDA Consumer Magazine, March-April 2007

The contamination of fresh spinach with the bacteria Escherichia coli (E. coli) O157:H7 during the fall of 2006 led to one of the largest and deadliest outbreaks of foodborne illness in recent years.

Most of the illnesses due to E. coli occurred from Aug. 26, 2006, to Sept. 16, 2006. Illnesses from spinach were confirmed in 26 states, and one case was confirmed in Ontario, Canada. In all, nearly 205 cases of illness were recorded during the outbreak, including 31 involving a type of kidney failure called hemolytic uremic syndrome (HUS). More than 100 people were hospitalized, and three deaths were recorded, including a 2-year-old boy in Idaho.

"One foodborne illness is too many," says Robert Brackett, Ph.D., director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN). "We've seen that there is no such thing as a small error when it comes to produce safety. Even what may be perceived as a small error can have disastrous consequences."

Fresh produce is especially vulnerable to contamination because it's grown in a natural environment. It may be grown in a field or orchard, and it is often consumed raw, without cooking or other treatments that could destroy bacteria and other pathogens.

The FDA works with many partners to prevent contamination, but it's impossible to eliminate all problems through prevention. "When there is a problem, we want to catch it early and contain it through efficient outbreak response," says David Acheson, M.D., director of food safety and security in the CFSAN. "In this case, the FDA mounted a collaborative effort with public health authorities throughout the country to identify the source of the problem and prevent its spread."

The CFSAN has the lead responsibility for ensuring food safety, regulating everything except meat, poultry, and processed egg products, which are regulated by the U.S. Department of Agriculture (USDA). The Centers for Disease Control and Prevention (CDC) has a complementary role, serving as the lead federal agency for conducting disease surveillance and outbreak investigations. Surveillance systems coordinated by the CDC, in collaboration with the states, provide an essential early-information network to detect dangers in the food supply.

Detecting an Outbreak

When a patient is diagnosed with E. coli O157:H7, a sample of the bacterial strain is sent to a participating PulseNet lab, says Christopher Braden, M.D., chief of outbreak response and surveillance at the CDC. PulseNet is a national network of public health laboratories that perform genetic fingerprinting on foodborne bacteria that result in human illness. Scientists use a process called pulsed-field gel electrophoresis (PFGE), a technique that subtypes bacteria.

"After the bacterial strain is subtyped or 'DNA fingerprinted' at a lab, the fingerprint is then uploaded electronically to the national PulseNet database where it can be compared with other patterns in other states," Braden says. "This gives us the capability to rapidly detect a cluster of infections with the same pattern occurring in multiple states. The strength of this system is its ability to identify patterns even if the affected people are geographically far apart."

Epidemiologists in Wisconsin were the first to alert CDC officials about a small cluster of E. coli O157:H7 infections on Sept. 8, 2006. At that time, the source of the problem was unknown. Wisconsin posted the bacterial strain to PulseNet to alert the entire network. PulseNet confirmed that E. coli strains from infected patients in Wisconsin had matching PFGE patterns and identified the same patterns in other states.
"Once a cluster of cases with the same DNA pattern is identified, epidemiologists interview patients to determine whether cases of illness are linked to a food source or what other exposures they have in common," Braden says.

Oregon's state health department also had noted a small cluster of cases and began interviewing patients. On Sept. 13, 2006, Wisconsin and Oregon health officials both notified the CDC that eating fresh spinach was reported. Most of those interviewed reported eating prepackaged raw spinach that came from a bag.
That same day, the CDC Director's Emergency Operations Center notified the FDA's Emergency Operations Center (EOC) of the possible association of prepackaged raw spinach to the illnesses. The FDA's EOC is the agency's focal point for coordinating and managing all emergencies involving products regulated by the FDA.

Alerting the Public

After learning from the CDC that fresh spinach was confirmed as the source of the outbreak, the FDA immediately took action to prevent further illness by alerting the public. On Sept. 14, 2006, the FDA and the CDC held a conference call with the states and issued a public alert, advising consumers not to eat bagged spinach at that time. Neither frozen nor canned spinach was implicated in the outbreak.

Those who had become ill reported eating various brands of bagged spinach, processed by Natural Selection Foods LLC of San Juan Bautista, Calif. One week after Wisconsin officials notified the CDC, Natural Selections, which bags spinach under several brand names, announced a voluntary recall. The company recalled all spinach products with a date code of Oct. 1 or earlier. Five more companies issued recalls between Sept. 15 and Sept. 22. "These secondary recalls occurred because Natural Selections had shipped spinach to other companies that repackaged it," Acheson says.

The companies that issued secondary recalls were RLB Food Distributors, L.P., of West Caldwell, N.J.; River Ranch Fresh Foods LLC of Salinas, Calif.; Kenter Canyon Farms Inc. of Sun Valley, Calif.; Triple B Corp., doing business as S.T. Produce of Seattle; and Pacific Coast Fruit Co. of Portland, Ore.

On Sept. 16, the FDA expanded its warning and advised consumers not to eat any fresh spinach or fresh spinach-containing products. "We expanded the advisory when we learned that bagged spinach was sometimes sold in an un-bagged form at the retail level," Brackett says. The FDA advised retailers and food service operators that they should not sell raw spinach or blends that may contain raw spinach.

"We were also concerned about fresh spinach products that could still be in consumers' refrigerators," Brackett says. "At that point, the priority was to prevent further illnesses. We wanted to get the word out and get fresh spinach off the shelves while we conducted an investigation to narrow down the source. The number of illnesses was increasing daily, which was alarming. And the reach was nationwide. We also knew that there were a significant number of severe illnesses and hospitalizations."

E. coli O157:H7 causes diarrhea, often with bloody stools. Though most people recover in a week, some are more vulnerable, especially very young children and older people. Of the 95 cases that had been reported by Sept. 15, 2006, almost half had been hospitalized, and 15 percent had HUS, a condition that can cause kidney damage and death.

The FDA's advice to not eat any fresh spinach remained in effect until Sept. 22, 2006, Brackett says, when the FDA became confident that the source of the tainted spinach was restricted to three California counties. On that day, the FDA advised the public that fresh spinach implicated in the outbreak was grown in Monterey, San Benito, and Santa Clara Counties. At the same time, the FDA said that spinach grown elsewhere was not implicated in the outbreak and could be consumed.

The Trace-Back Investigation

From the first indications that fresh spinach was the culprit in the fall 2006 outbreak, investigators from the FDA, the CDC, and the states worked together to trace the implicated spinach back from consumption to the fields. The fact that illnesses were reported in multiple states suggested that contamination likely happened early in the distribution chain.

"Traceability to the farm is absolutely critical," says Jeff Farrar, D.V.M., Ph.D., chief of the Food and Drug Branch in the California Department of Health Services (CDHS). "We have seen many processors in the past who believed they had state-of-the-art traceability systems and when outbreaks occur, they realize their systems are not nearly as good as they thought."

On Sept. 14, 2006, Erica Pomeroy, an investigator in the San Francisco District of the FDA's Office of Regulatory Affairs, was already in the Salinas Valley with James Sigl, a senior investigator with the CDHS. The Salinas Valley is in the central coast region of California, about 55 miles south of San Jose and 20 miles northeast of Monterey.

"We were there conducting an assessment of a grower when we got a call that we needed to go to Natural Selections to start an investigation," Pomeroy says. They were in the area as part of the FDA's Lettuce Safety Initiative, which calls for assessments of growing and harvesting practices in major growing areas of leafy greens during September and October—months when outbreaks have occurred in the past. It took Pomeroy and Sigl about 45 minutes to drive to Natural Selections, where they reviewed the spinach washing and packaging process and collected documents from the company to determine which fields should be investigated.

Serving as team leaders for the investigation, they set up a command center at a hotel near the Salinas Valley. They were soon joined by other members of the California Food Emergency Response Team (CalFERT), a collaboration between the FDA's Pacific Region and the CDHS. CalFERT includes a diverse team of investigators, food scientists, environmental scientists, microbiologists, and chemists.

"Having the right people with the right skills available on site is critical to any successful investigation," says Barbara Cassens, the FDA's San Francisco district director. "By training the CalFERT staff together and offering them an opportunity to develop a working relationship prior to an emergency, we were able to move quickly in this outbreak response."

Pomeroy says the command center served as a place where they could have computer access and convene to share information, review findings, and plan strategies. "By focusing on fields

associated with certain production lots, we were able to narrow the search to nine different ranches in the area," Pomeroy says. "We interviewed harvesters and growers about growing practices, irrigation practices, and their workers. We collected samples in and around the suspect fields from every possible source of contamination—water, soil, and domestic and wild animal feces." Labs of the FDA, the CDHS, and the USDA were able to process about 900 samples in a relatively short time.

And while investigators were conducting investigations on the farm level, other experts continued to analyze data collected in spinach questionnaires of people who had gotten ill. "The FDA collaborated with CDC to design a spinach questionnaire, a tool used to elicit a detailed history of spinach consumption from people who became ill," says Karl Klontz, M.D., a medical officer in the CFSAN. "We worked with CDC to analyze data collected using information such as brand name, date of purchase, Universal Product Code (UPC) code, and lot numbers."

A Break in the Case

On Sept. 20, 2006, a big break came when New Mexico's public health laboratory announced that it had isolated the outbreak's strain of E. coli O157:H7 from an open package of spinach that came from the refrigerator of a patient who had become ill. "The package of spinach that tested positive was Dole baby spinach best if used by August 30," Klontz says. This was a tremendous help in tracing back to the fields. Later, the strain implicated in the outbreak also was isolated from open packages of fresh spinach consumed by ill people in several other states, including Utah, Pennsylvania, Colorado, Ohio, and Wisconsin.

In the end, the focus of the trace-back investigation narrowed to four fields on four different ranches. On Sept. 29, 2006, the FDA announced that all spinach implicated in the outbreak traced back to Natural Selection Foods.

Possible Routes of Contamination

The investigation into how the spinach may have become contaminated included sample collection in facilities and a review of animal management practices, processing practices, and water use. Richard Gelting, Ph.D., an environmental engineer from the CDC's National Center for Environmental Health, was deployed to California at the FDA's request to join in the investigation of possible environmental sources of contamination. He investigated irrigation well structure, ground water movement, and water management practices in the implicated farm regions.

On Oct. 12, 2006, the FDA and the state of California announced test results. The field investigation discovered the same strain of E. coli O157:H7 involved in the illnesses in environmental samples collected at one of four implicated ranches that supplied spinach to Natural Selection. The samples included water from a stream and cattle feces taken from pasture areas on the ranch outside the crop fields. The E. coli O157:H7 isolates from these samples were matched to the outbreak strain by their PFGE patterns. Wild pig feces collected by investigators on the ranch were also found to contain this same strain of E. coli O157:H7.

"One unusual finding on the ranch was a high population of wild pigs," says Farrar. "But we haven't determined conclusively that wild pigs were the source of the contamination. Finding an exact-matching E. coli strain on an implicated farm is a first in California, and it directly reflects the CALFERT approach. But we still don't know how the pathogen came into contact with the spinach."

Fencing around the cow pastures nearby appears to keep the cows from going into the spinach fields. But Gerald Wiscomb, an expert on the team from the USDA's Wildlife Services, observed during his behavioral studies that pigs go into the crop fields on the ranch. "There are many possibilities," Pomeroy says. "It could be that the pigs rooted around the cow feces, contaminating themselves, and then later defecated in the spinach fields." Another possibility is that surface contamination from pig and cow feces in the pasture areas got into the ground water.

More research is needed to better understand how E. coli O157:H7 is introduced into the environment, says Farrar. "We need a better understanding of how the organism survives, whether it grows in certain conditions, exactly how it comes into contact with ready-to-eat products, and how it's affected by current processing practices," he says.

History of Outbreaks in the Salinas Valley

Produce-related outbreaks have been a continuing problem in recent years. Since 1995, there have been 20 outbreaks involving leafy greens, most traced to California. Many, but not all, were traced to the Salinas Valley. But there aren't definitive answers as to why many of these outbreaks are linked to the Salinas Valley, according to experts.

"Some have speculated that the reason other areas have not been implicated is simply because of the difference in the volume of production," Farrar says. "The Salinas Valley produces much more leafy greens than any other area in the country so we may be more likely to see outbreaks from this area. Others believe there are one or more unidentified geographic, topographic, or environmental risk factors unique to Salinas Valley that result in systemic contamination with E. coli O157:H7."

In a recent multiagency investigation project, the CDHS discovered many E. coli O157:H7 positive findings in agricultural ditch water in many area locations. This is the runoff water originating in the hills surrounding the Salinas Valley. Although none of these isolates have matched any known outbreak strains, these findings have resulted in a grant from the USDA's Agricultural Research Service to the University of California at Davis (UC-Davis) and the CDHS to look further into environmental sources of contamination in this area.

Industry and FDA Action

In 2004 and 2005, the FDA wrote to industry to express both the agency's concerns with continuing outbreaks and its expectations for industry to improve produce safety. One letter to the lettuce and tomato industries in February 2004 encouraged industry to review practices in light of the FDA's Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) guidance. Another letter, sent in November 2005, reiterated this concern and focused on fresh-cut lettuce and other leafy greens.

After the most recent spinach outbreak, the FDA and the state of California asked the produce industry to develop a comprehensive plan to minimize the risk of another outbreak due to E. coli in spinach grown in California.

The Grower-Shipper Association of Central California, the Produce Marketing Association, the United Fresh Produce Association, and the Western Growers Association pledged their commitment and submitted a draft plan to the FDA.

Implementation of this plan is voluntary, but the FDA and the state of California may institute regulatory requirements if it is determined that they are needed.

The Public Health Service Act authorizes the FDA to make and enforce regulations to prevent the introduction, transmission, or spread of communicable disease. And the Federal Food, Drug, and Cosmetic Act provides a broad statutory framework for federal regulation to prevent adulterated foods from entering commerce, and to ensure that human food will not be hazardous to health.

Farrar says that industry also has proposed the creation of a statutorily based "Marketing Order and Marketing Agreement" on the state level for growers and processors as a possible avenue. "We are familiarizing ourselves with this proposal for mandatory and uniform standards for leafy greens industry in California that would be administered under the California Department of Agriculture's statutory authority," he says.

The FDA and the state of California have reiterated previous concerns and advised firms to review their operations in light of the FDA's guidance for minimizing microbial food safety hazards, as well as other available information regarding the reduction or elimination of pathogens on fresh produce.

Charles Sweat, chief operating officer of Natural Selection Foods, announced that his company will require a number of measures be taken by growers that supply their company with the fresh-cut produce that they pack. These measures include working with growers from seed to harvest, inspecting the seed, irrigation water, soil, plant tissues, and wildlife. The company also indicated that sanitation protocols for farm equipment and packaging supplies will be enhanced and monitored, and that a "firewall" will be set up to test all the freshly harvested greens before they enter the production stream.

"Clearly things have to change throughout the leafy greens industry and the changes need to occur quickly," Farrar says. "We have relayed to industry that the solution must include specific, measurable, enforceable on-farm food safety practices that are based on the best science that's available now."
According to GAP guidelines, areas that should be considered to minimize the potential for microbial contamination of produce include

* agricultural water used for irrigation or crop protection sprays
* wild and domestic animals
* worker health and hygiene
* the production environment, which includes the use of manure, previous land use, and use of adjacent land
* post-harvest water used to wash or cool produce
* sanitation of facilities and equipment.

The Produce Safety Plan

The FDA instituted a Produce Safety Action Plan in 2004. The action plan builds on previous guidance and addresses microbial food safety hazards and good agricultural and management practices common to growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or raw (minimally processed) form.

The plan contains four objectives: preventing contamination of fresh produce with pathogens; minimizing the public health impact when contamination of fresh produce occurs; improving

communications with producers, preparers, and consumers of fresh produce; and facilitating and supporting research relevant to fresh produce.
"A significant change is that we've gone from a broader-scope guidance in the past to more commodity specific guidance," says Nega Beru, Ph.D., director of the CFSAN's Office of Plant and Dairy Foods. "Certain commodities account for most of the foodborne outbreaks associated with produce."

As part of the plan, the FDA has provided technical assistance to help industry develop food safety guidance for five commodity groups: cantaloupes, lettuce and leafy greens, tomatoes, green onions, and herbs. The guidelines for cantaloupes, tomatoes, and lettuce have been finalized and are available. With FDA assistance, industry work on guidances for herbs and green onions is ongoing.

In March 2006, the agency released draft guidance for the fresh-cut produce industry. The agency is working to finalize its "Draft Guidance to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables." The Lettuce Safety Initiative, developed in August 2006, supports the produce safety plan and covers lettuce and other leafy greens, including spinach.

In August 2006, the FDA met with Virginia officials to discuss outbreaks associated with tomatoes produced on the Eastern shore of Virginia. The FDA worked with the Florida Tomato Exchange and the University of Florida's Institute of Food and Agricultural Sciences to arrange a forum, held in November 2006, to discuss improving tomato safety. Also in November 2006, the FDA announced results of an investigation by state and CDC investigators which found that consuming tomatoes in restaurants was the cause of illnesses of *Salmonella Typhimurium*. Twenty-one states reported 186 cases of illness to the CDC.

"Produce safety is the number one priority in CFSAN right now," Brackett says. "Our role is to serve as a leader in providing direction for industry and to apply the best science-based approaches toward building an even safer food supply. As a result of effective collaboration with our public health partners, the American food supply continues to be among the safest in the world. But we also know that we must continue to work on reducing the incidence of foodborne illness to the lowest level possible."

5 faces. 5 agonizing deaths. 1 year later.
Spinach recall improved food safety -- but is it enough?

Elizabeth Weise, Julie Schmit, USA TODAY, September 21, 2007

Ruby Trautz was the first to die.

On Aug. 27, 2006, the 81-year-old Nebraska woman was rushed to the hospital. She was in so much pain that morphine was administered. Four days later, she succumbed to a food-borne infection later identified as a virulent strain of E. coli.

Two weeks after Trautz's death, on Sept. 14, the Food and Drug Administration took an unprecedented step: It told Americans to stop eating bagged spinach, a staple of healthy diets, until its safety could be assured. A day later, the FDA extended the warning to include all fresh spinach and almost as quickly, it vanished from grocery shelves, salad bars and menus.

By this time, two more people had died.

Before the outbreak of E. coli O157:H7 was over, at least five people were dead after painful, bloody illnesses. More than 205 others in 26 states had endured a sickness that left them vulnerable to future health problems. And the agricultural industry, government regulators and consumers were shaken by the vulnerability of America's system for delivering fresh produce to markets.

Since early this year, USA TODAY has interviewed dozens of key government officials, food producers, survivors who ate contaminated spinach and relatives of those who died. They offer new insight into the behind-the-scenes panic throughout the agricultural industry and government offices as the crisis unfolded nationwide, and of the detective work that led officials to suspect that the E. coli -- commonly found in cow manure -- came from spinach grown on a 2.8- acre plot in central California.

The FDA would partially lift the spinach advisory on Sept. 22, but it would be six months before federal and state investigators released their report.

The outbreak would ultimately cost the leafy green industry more than $350 million as the nation turned away from its growing appetite for fresh, ready-to-eat spinach. It's an appetite that has not returned: Sales of packaged spinach are still off about 20% from pre-outbreak levels, industry executives say.

The interviews reveal vivid details of the gruesome illnesses caused by the contaminated spinach, and show why such a deadly crisis remains possible today. In the past year, the industry has made strides in keeping produce safe, says Michael Doyle, head of the Center for Food Safety at the University of Georgia and a consultant to Natural Selection Foods, which processed the tainted spinach.

But while companies have imposed higher standards for farmlands and have increased testing of the greens before they get to the consumer, it's still possible for bacteria to get through the safety net.

In the past four weeks there have been two leafy green recalls, one for E. coli in mixed greens and another for *salmonella* in spinach. No illnesses were reported.

"Raw produce, even if you put it in a bag and seal the bag, is still raw produce. It's a high-risk food, even if the American consumer doesn't realize it is," says Oregon state epidemiologist William Keene.

One year ago, that risk changed families, an industry and consumer attitudes toward fresh spinach.

The victims

In July, the month before Trautz died, a 2.8-acre section of a 51- acre field was planted in spinach by grower Mission Organics at the Paicines Ranch in central California, an 8,000-acre spread largely devoted to cattle grazing.

The 1,002 pounds of spinach from that 2.8-acre section was harvested on Monday, Aug. 14, and processed the next day by Natural Selection Foods, one of the nation's biggest processors of leafy greens. The spinach went mostly into bags of Dole Baby Spinach, each tagged with the production code P227A. It was shipped nationwide.

FDA and California investigators would later say that spinach from this small section of the Paicines Ranch most likely carried the deadly E. coli strain into the homes of unsuspecting consumers.

They were consumers such as Polly Costello, who on Monday, Aug. 21, bought a package of Dole Baby Spinach at No Frills Supermarket in Bellevue, Neb. She, her husband and her mother, Ruby Trautz, would eat spinach from the bag over the next few days.

By that Saturday, Trautz was sick with nausea, vomiting, abdominal cramps and diarrhea. On Sunday she began passing blood, and her daughter and son-in-law rushed her to Creighton University Medical Center in Omaha.

When a nurse examined her on Sunday, Aug. 27, Trautz was light- headed and in extreme pain. On Thursday, after five days of increasing weakness, Trautz began to hallucinate and have seizures. She died at 6:15 a.m. that day.

Her doctors had no idea what had killed her. It wasn't until Sept. 25 that tests on the spinach from her daughter's refrigerator showed she had been infected with E. coli O157:H7.

The second death came Sept. 7, a week after Trautz's, when 77- year-old Marion Graff of Manitowoc, Wis., succumbed to kidney disease. Graff had always been a healthful eater. "My mother would cover her plate in salad," says her daughter, Leah Duckworth.

A woman who'd blossomed with age, Graff was with friends on a bus trip to Minneapolis for a weekend of museums and theater when she lost consciousness.

Graff deteriorated so quickly that Duckworth, on vacation in Canada, couldn't get home in time. Her sister, Annie Banks, held the phone to their mother's ear and Graff said, "I love you, my little mommy. Now it's time." Their mother died about 90 minutes later.

Next was June Dunning who, even at 86, was "a very proper British lady" who made a point of leading a healthy life, says her son-in- law, Chuck Swartz. Dunning lived with Swartz and her

daughter Corinne in Hagerstown, Md. She got sick Friday night, Sept. 1, several days after eating lightly steamed spinach from a Dole bag. True to her stiff-upper-lip nature, Dunning didn't bother her family about the pain.

The next morning Corinne went into Dunning's room "and found this huge bloody mess all over," Swartz says. Corinne took her mother straight to the hospital.

It wasn't until Wednesday, Sept. 6, that tests showed she had E. coli O157:H7. "I said, 'What's that? That sounds like something from Mars,'" her son-in-law says. "The infectious-disease doctor said it came from hamburger. We said, 'She doesn't eat hamburger; she loves vegetables.'" Dunning lasted for another week.

The fourth fatality was the youngest, 2-year-old Kyle Allgood of Chubbuck, Idaho. Kyle had been born at home before his mom and dad could make it to the hospital. "He was in a hurry coming into this world, and he was in a hurry to leave it," says his mother, Robyn Allgood.

Kyle came down with flu-like symptoms on Friday, Sept. 15. His mom had worked hard to make sure her kids got good nutrition. A favorite trick was the veggie smoothie. "If you put enough berries and juice and yogurt in them, you can put spinach in, so I did," she says.

But it soon became clear that Kyle had something much more serious than the flu. The whole family got sick, but his mom, dad and his older sister fought it off. Kyle couldn't. He was rushed to the local hospital, then to Primary Children's Medical Center in Salt Lake City.

There, Kyle developed hemolytic uremic syndrome (HUS). His kidneys shut down. On Wednesday, Sept. 20, he had a heart attack and died, his parents at his bedside.

The last death occurred on Jan. 26, 2007, when Betty Howard of Richland, Wash., succumbed to heart failure after a long battle with HUS. Howard, 83, got sick after eating a turkey sandwich garnished with spinach. She went into the hospital on Sept. 7 and from there to a convalescent facility, never returning home.

Howard and Dunning were not counted in the Centers for Disease Control and Prevention's final list of victims. Seattle-based Bill Marler, considered the nation's pre-eminent E. coli lawyer, who represents Howard's and Dunning's families, says the bacteria that felled both matched the spinach outbreak strain. Their medical bills were paid by Natural Selection's insurer, Marler and Dole say. Natural Selection declined to comment.

Dozens of others would become dangerously ill. Of the 200 confirmed cases of sick people, 102 were hospitalized and about 15% would suffer kidney failure -- a condition that could affect them for the rest of their lives.

In Milwaukee, two of Ana Maria Zientek's children, David, then 6, and Caroline, then 3, were sickened by the spinach salad they'd eaten at dinner on Aug. 28, suffering severe cramps and diarrhea.

Blood "literally poured" out of Caroline as her mom bundled her up in a sheet and raced to the hospital. David was hospitalized for six days, his sister for 13.

For Jillian Kohl of Milwaukee, the nightmare began on Wednesday, Aug. 30, with a spinach salad. Being a thrifty grad student, she ate a lot of it, because the expiration date on the bag was that day.

Over the next few days the 25-year-old marathon runner started to feel tired and worn out. By the weekend she was feverish and nauseated. She called her mother, who told her to rest and take aspirin. But on Monday, the bleeding started, putting her in a hospital's intensive care unit for eight days.

At one point, as her body began to shut down, she thought, "I give up. I had a good 24 years in life, and I hate that my family is going to have to see me die like this."

The regulators

In the early days of the outbreak, Wisconsin and Oregon, both known for their strong public health departments, took the lead in trying to figure out what was making people sick.

Wisconsin, which has an aggressive E. coli monitoring network, was the first state to realize that something was wrong.

When the week of Sept. 4 began, chief state epidemiologist Jeffrey Davis knew that he had a cluster of five E. coli O157:H7 cases. But most of the victims had gone to the Manitowoc county fair -- a common place for E. coli to spread, because cows and other animals excrete the bacteria in feces.

And small clusters aren't uncommon; in any year Wisconsin may have around 200 cases. Davis adopted a wait-and-see approach.

But there was one confusing twist. Graff, who would become the second fatality, hadn't gone to the fair.

By midweek, there was an outbreak in another county, and a pattern was emerging. On Thursday, Sept. 7, the day Graff died, the director of the BloodCenter of Wisconsin told Davis he'd gotten requests for plasma for five people at five hospitals, all of whom had HUS. "That was very, very unusual," Davis says.

Wisconsin confirmed that all the hospitalized people had the same strain of E. coli O157:H7 and posted three of the test results Friday to PulseNet -- a national database launched in 1998 that allows public health officials nationwide to track food-borne illnesses.

Davis then called Chris Braden, chief of the Outbreak Response and Surveillance Team at the CDC, to alert the federal agency.

By themselves, the Wisconsin cases didn't mean much. "There's always a certain number of background cases," says Robert Tauxe, chief of the food-borne and diarrheal diseases branch at CDC. In August, for example, PulseNet had had nine different E. coli strains from nine states.

The Wisconsin cases were different from the usual, unrelated cases but no one knew that yet. But they were now out there, waiting to see if anyone, anywhere else in country, was also infected with the identical E. coli strain.

By Tuesday, two other states had posted matches, PulseNet records show.

On Wednesday, Sept. 13, Robert Brackett, head of the FDA's Center for Food Safety, got an e-mail from Wisconsin asking if there was contamination reported in lettuce.

As lettuce had been the major source of more than a dozen O157:H7 outbreaks, it was a good question. But the FDA wasn't tracking anything in lettuce, so the answer was "no."

Oregon had a little E. coli cluster going, as well. But it wasn't initially viewed as a big deal -- until Sept. 13. Melissa Plantenga, an investigator, told senior epidemiologist William Keene that of the six people who were sick, five said they'd eaten bagged spinach, although they named four different brands.

Keene wasn't surprised: Fresh spinach was a very plausible vehicle for E. coli O157:H7 because there is no guaranteed "kill step" in readying it for consumption. Bagged salads are washed and re-washed in processing plants, making them safe to eat straight from the bag, companies say. But the wash doesn't eradicate all bacteria.

Keene might have reacted more forcefully if he'd been able to check PulseNet and see that other states were reporting E. coli cases, too.

But he couldn't do that because the state had been bounced off PulseNet. A CDC-issued device that generates the security codes that allow states to log into the computer network had expired and the new one hadn't yet arrived in the mail.

Keene called officials in California, where most of the nation's leafy greens are grown, and learned that it isn't unusual for multiple brands of packaged bags to come from the same plant.

It was all falling into place. Keene pounded out a somewhat cryptic e-mail to the CDC: Oregon had a cluster of O157:H7 cases, and he wondered if anyone else was seeing anything similar. Ten minutes later, the CDC e-mailed him back, saying yes, there were a lot of other cases out there.

So Keene also called Braden, the CDC's top food-borne illness epidemiologist. Wisconsin's Davis was patched in, and the three men began comparing what they knew. "At that point, Phase One of the investigation was over," Keene says. Wisconsin and Oregon had shown the outbreak was O157:H7 from spinach. Within 24 hours, the rest of the nation would know as well.

That day, June Dunning died in Maryland.

That night the CDC asked all 50 state public health departments if anyone else was seeing E. coli cases. The next morning, Sept. 14, the CDC had heard from eight states reporting 50 cases. It was looking like a nationwide problem.

By noon, CDC and FDA officials were having their own conference call with their state counterparts. The CDC asked each of the eight states to list the number of cases, the number of hospitalizations, how many kids, how many with HUS and how many dead. The FDA's chief medical officer, David Acheson, took notes.

"I'm writing this all down, and I get to page three and I'm thinking, 'Oh dear,'" he says. For every reported case, he knew there would be many more that hadn't yet been reported or noticed by state health officials.

Some states had sick consumers reporting eating lettuce; some said strawberries. But more said spinach, even bagged spinach with household-brand names on it, including Dole.

Indeed, 80% of the consumer cases at that time recalled eating spinach, an incredibly high number to be coincidental as only about 17% of the U.S. population routinely eats spinach.

The call lasted at least two hours. At the end of it, "We were looking at each other saying, 'This was big,'" Acheson says.

The FDA team met in what would become their war room, a slightly worn conference room on the 12th floor of the Office of Emergency Operations at the agency's Rockville, Md., offices.

In the next two hours, the 10 or so people in that room would decide to tell the American people to stop eating a single product. Not a brand. Not a lot number. Not a production day. An entire product -- bagged spinach.

The FDA, concerned that consumers may not know if bagged spinach was dumped out of bags and into loose-leaf bins at grocery stores, expanded the advisory the next day, Sept. 15, to cover all fresh spinach.

The pronouncement was so big that FDA lawyers questioned the agency's press officer, Julie Zawisza. She remembers them asking: "Do you realize that you're saying, 'Don't eat any raw spinach from any source, anywhere, anytime?'"

The FDA did, Zawisza responded, and the media onslaught began.

Acheson was driving home when he got a call: CNN wanted to do a phone interview. When would he be home? He finally dropped off to sleep shortly before midnight. One of his lingering thoughts: "Could this have been deliberate?"

The industry

The news hit the processors and growers of America's $3.5 billion packaged-salad market hard. In California's Salinas Valley, nicknamed "America's salad bowl," producers of leafy greens gaped at CNN as they listened to the FDA's warning that an E. coli outbreak was likely underway.

Executives -- scattered on Sept. 14 -- quickly got back to their offices. Dole Fresh Vegetables President Eric Schwartz was on the East Coast for a business trip. Natural Selection President Charles Sweat was in San Diego visiting customers. Both immediately caught flights home.

Tanios Viviani, president of Fresh Express, the biggest maker of packaged salads in the USA, turned on CNN and learned that a big part of his industry had been shut down. "It was like an earthquake," he says. "I was thinking to myself: 'Why am I learning about this from CNN?'"

Barbara Cassens, district director of the FDA's San Francisco office, got on the phone with executives from companies that made or sold spinach that sick consumers reported eating: Dole, River Ranch and Natural Selection.

For Sweat, one tidbit from that conversation would plunge his company into the biggest crisis of its 22-year history: About 6 out of 10 consumers who reported illnesses thought they'd eaten Dole spinach. Natural Selection made that product.

California officials suggested a recall, Sweat says. The next day, Natural Selection recalled products made at its plant in August and September for 28 brands, including Dole. None other than the Dole Baby Spinach processed by Natural Selection would ever test positive for the E. coli outbreak strain.

In fact, the contaminated produce appears to have been concentrated in 42,000 bags of Dole Baby Spinach processed during a single shift in one plant.

The recall was much bigger because, at the time, no one was sure how many products or processors were involved. Within seven days of Natural Selection's recall, five more companies would recall produce. All had products made for them by Natural Selection.

As soon as the outbreak was confirmed, investigators began hunting for production records that could lead back to the point of contamination, something that had never been accomplished in 19 previous E. coli leafy-green investigations since 1995.

Everyone in the Salinas Valley produce community was fearful, says Bradley Sullivan, a lawyer for grower Mission Organics, which would later be identified as the most likely grower of the tainted spinach.

Sullivan says growers and processors were on the phone constantly, sharing rumors and details. "In those first days, everybody was nervous. All the processors. All the growers," he says. "They were asking, 'If it is me, could I go to jail?'"

Otto Kramm, managing partner of Mission Organics, which is 85% owned by the same investors who own two-thirds of Natural Selection, was feeling pretty safe, Sullivan says. He thought his spinach had been harvested too late to make it into bags that were beginning to sicken people on Aug. 23. "We thought it would still be sitting in a cooler somewhere," Sullivan says.

That would turn out to be a wrong assumption. Of the 850 soil, water and feces samples collected by California and FDA investigators, only those from the Paicines Ranch, where Mission Organics farmed, would match the outbreak strain.

None of that was known on Sunday, Sept. 17, when executives from Natural Selection, River Ranch and Fresh Express, which by now had also been named by sick consumers, met at the Residence Inn in Salinas with regulators.

The dozen participants, in casual dress, rearranged the tables in the hotel's meeting room into a horseshoe shape so they could see each others' faces. Some executives had boxes of production records before them, says Jim Lugg, food safety chief at Fresh Express, which had prepared a one-page document explaining how it would gather electronic records. The doors were shut, and then there was silence.

No one knew how to get started as "we were all equals," Lugg says. By the time the one-hour meeting ended, the companies had told the officials how they would gather production records for the past three months. Lugg suspects the officials had expected to get them that day.

That, too, would turn out to be a wrong assumption.

The investigation

With at least three processors to check out, it would take almost two weeks for investigators to narrow their search from 12 fields to the final four. Investigators even pulled empty spinach bags out of consumer garbage cans to get clues. "It was like a big treasure hunt," says the FDA's Cassens.

Indeed, tracing the contaminated produce that people ate back to the greens processed by Natural Selection and the field they came from involved thousands of pages of documents, some handwritten.

Even with a record in hand, Kevin Reilly, then an investigator for the California Department of Health Services, says investigators must verify that what is on the record jibes with what plant managers and workers say happened. "It is a CSI-like investigation," he says, referring to the popular CBS show.

A big break came on Sept. 20, when researchers in New Mexico proved that the strain of O157:H7 from the P227A Dole bags of spinach was identical to the strain that was infecting people. The code indicated the product was made at Natural Selection's south plant (P) on the 227th day of the year, (Aug. 15) on the first of two shifts (A). "It was the first time we had a code, a bag of product and an E. coli match," says the FDA's Cassens.

That was also the day on which 2-year-old Kyle Allgood died.

Even with the confirmed P227A code, Cassens says it would take investigators seven days of poring through records to narrow the investigation to what turned out to be the four ranches that supplied the P227A product.

On Sept. 22, the FDA felt confident enough to tell consumers that it was safe to eat spinach grown outside three California counties: Monterey, San Benito and Santa Clara. The contaminated product, it was later discovered, most likely came from San Benito and the 2.8- acre slice of the 51-acre field on Paicines Ranch.

That entire field now sits fallow along a lonesome stretch of highway that cuts through a narrow valley between hillsides covered in brush and grass. Natural Selection says an extensive risk assessment will be done before it will be considered for leafy greens again.

The grower, Mission Organics, didn't have an outside company check the field's food-safety risks before last year's outbreak, investigators said. Sweat of Natural Selection says the company requires such third-party audits for every ranch that supplies it, and now checks to make sure its growers comply.

FDA and California investigators issued their report on March 23, almost two months after the death of Betty Howard. They didn't pinpoint how the spinach was tainted, saying the culprits that carried the O157:H7 might have been wild pigs that lived near the field or irrigation water from wells not grouted to prevent seepage from groundwater exposed to feces.

The investigators also said there was no evidence that the contamination started at the Natural Selections plant. But they said conditions inside the plant may have allowed pathogens to spread.

There were no indications that the contamination was the product of a deliberate act.

Epilogue

This outbreak was home-grown, unlike the most recent spate of food-safety scares involving products from China, which have re- ignited concerns about the nations' food-safety defenses. State and federal health officials say they will respond more forcefully because of the lessons learned in the E. coli outbreak.

Since last fall, companies have taken thousands of acres out of leafy-green production because they've been deemed too close to pastures, wildlife or other risk factors -- and they've added miles of fencing, including on the Paicines Ranch.

Processors in California, where the bulk of the nation's leafy greens are grown, have also agreed not to buy from growers who don't meet a defined set of safety standards -- an industry first.

Some companies are improving their ability to track a bag of produce back to where it was grown. That will aid investigators and help limit the size of recalls. Dole is implementing a high-tech system that it says will enable it within minutes to track a contaminated bag back to within 30 feet of where the product was grown in the field.

Companies are also doing more testing for E. coli and *salmonella* in raw, leafy greens and, for the first time, in the finished product, too.

While some companies say such testing may provide a false sense of security because such a small percentage of the product is actually tested, just such a system late last month may have prevented another illness outbreak caused by contaminated spinach.

California's Metz Fresh retrieved more than 90% of 8,118 cases of potentially *salmonella*-contaminated bagged spinach before they got to consumers. Metz had tested the bagged produce as it came off the processing line and detected *salmonella*, leading to a recall.

In the past, the *salmonella* may never have been detected until someone got sick. No illnesses were reported, the company says.

Parts of the industry -- and some lawmakers -- have advocated that the FDA, which already regulates processing plants, start to oversee growers. The FDA's Brackett says the establishment of mandatory federal rules for growers has been discussed as one of several options related to produce safety.

For some, this will never be over.

Milwaukee's Jillian Kohl has resumed her graduate studies in art therapy, which were interrupted in their first week by her hospitalization. Her kidney function is normal now, but her doctors say there is a 30% chance that in the next 10 to 20 years they could fail again

"By the time I am 40 to 45 years old, I could be laying in a bed hooked up to dialysis machines again. I know death is inevitable, but sometimes it feels like quite a load to carry, knowing a rough timeline has potentially been put on my life," she says.

Kyle Allgood's family decided not to sue Dole. "We really trust in God," his mom, Robyn, says. "We felt that if he'd meant for Kyle to stay, he would have helped him fight it."

Natural Selection's Sweat says he learned of Kyle's death on the eve of his 45th birthday. "That was the one that took me to my knees," he says. "I was on my knees, in my home."

After Kyle died, the Allgoods' neighbors held a bake sale to buy benches in Kyle's name for a park in which he and his little sister played. Robyn wasn't sure she could walk past that park with her oldest daughter when school started this year. It was just too painful. But two weeks ago she did and was buoyed by what the benches represented.

"It's all the love there. I just don't think people understand what that meant to us."

For Zientek, grocery shopping is a different experience today. "We were somewhere, and my children naturally reached for some lettuce that was there and I had to stop myself from saying, 'No, put that down,' as if it was something really bad." She sighs. "I don't want them to grow up like that."

While the kids are healthy today, they, too, carry a greater risk for kidney disease and will need to be tested for the rest of their lives.

"People think life goes on," Zientek says. "But you're never really the same."