Produce in public: Spinach, safety and public policy

by

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Introduction

In October, 1996, a 16-month-old Denver girl drank Smoothie juice manufactured by Odwalla Inc. of Half Moon Bay, California. She died several weeks later. 64 others became ill in several western U.S. states and British Columbia after drinking the same juices, which contained unpasteurized apple cider contaminated with Escherichia coli O157:H7. Investigators believed that some of the apples used to make the cider might have been insufficiently washed after falling to the ground and coming into contact with deer feces (Leiss and Powell, 1997).

Almost 10 years later, on Sept. 14, 2006, the U.S. Food and Drug Administration (FDA) announced that an outbreak of E. coli O157:H7 had killed a 77-year-old woman and sickened 49 others (United States Food and Drug Administration, 2006). The FDA learned from the Centers for Disease Control and Wisconsin health officials that the outbreak may have been linked to the consumption of produce, and bagged fresh spinach was identified
as a possible cause (Bridges, 2006a).

In the decade between these two watershed outbreaks, almost 500 outbreaks of foodborne illness involving fresh produce have been documented, publicized and led to some changes within the industry. Yet what author Malcolm Gladwell (2000) would call a tipping point ("a point at which a slow gradual change becomes irreversible and then proceeds with gathering pace," (Anonymous, 2008)), public awareness about produce-associated risks did not reach a tipping-point until the spinach E. coli O157:H7 outbreak in the fall of 2006. At what point did sufficient evidence exist to compel the fresh produce industry to embrace the kind of change the sector has heralded since 2007? And at what point will future evidence be deemed sufficient to initiate future changes in any industry?

\$a\$ Research on North American outbreaks

Fresh fruits and vegetables were identified as the source of several outbreaks of foodborne illness in the early 1990s, particularly leafy greens (Table 1).

\textbf{Table 1 here}

Although poor employee hygiene was responsible for over 40% of source identified produce-related outbreaks (Bean and Griffin,
1990), produce can also be contaminated due to internalization of pathogens both through the root system and flesh or stem scars. Evidence of infiltration of bacteria into vegetables has been reported (Bartz, 1982; Bartz and Showalter, 1981; Burnett and others, 2000; Seo and Frank, 1999; Zhuang and others, 1995) and substantial evidence exists to conclude that pathogens can become incorporated into fresh produce. Previous research, for example, suggests that pathogens can enter lettuce plants through its roots and end up in the edible leaves. Small gaps in growing roots through which plant pathogens infect tissue may also allow E. coli entry (Solomon and others, 2002b; Warriner and others, 2003a; Warriner and others, 2003b). This research has been well known and publicized in mass media.

The 1993 outbreak of E. coli O157:H7 associated with undercooked hamburgers at the Jack-in-the-Box fast food chain propelled microbial food safety to the forefront of public awareness, at least in the U.S. (Leiss and Powell, 1997). In 1996, following extensive public and political discussions about microbial food safety in meat, the focus shifted to fresh fruits and vegetables following an outbreak of Cyclospora cayetanesis linked to Guatemalan raspberries that sickened 1,465 in 21 U.S. states and two Canadian provinces (CDC, 1997). That same year, Beuchat (1996) published a review on pathogenic microorganisms
in fresh fruits and vegetables and identified numerous pathways of contamination.

By 1997, researchers at CDC were stating that pathogens could contaminate at any point along the fresh produce food chain, at the farm, processing plant, transportation vehicle, retail store or foodservice operation and the home, and that by understanding where potential problems existed, it was possible to develop strategies to reduce the risks of contamination (Tauxe and others, 1997). Researchers also reported that the use of pathogen-free water for washing would minimize risks of contamination (Suslow, 1997; Beuchat, 1998).

Beuchat and Ryu (1997) reported in a review that sources of pathogenic microorganisms for produce included:

**Preharvest**
- Feces
- Soil
- Irrigation water
- Water used to apply fungicides, insecticides
- Green or inadequately composted manure
- Air (dust)
- Wild and domestic animals (including fowl and reptiles)
- Insects
- Human handling
Postharvest

- Feces
- Human handling (workers, consumers)
- Harvesting equipment
- Transport containers (field to packing shed)
- Wild and domestic animals (including fowl and reptiles)
- Insects
- Air (dust)
- Wash and rinse water
- Sorting, packing, cutting, and further processing equipment
- Ice
- Transport vehicles
- Improper storage (temperature, physical environment)
- Improper packaging (including new packaging technologies)
- Cross-contamination (other foods in storage, preparation, and display areas)
- Improper display temperature

In response to outbreaks and academic publications, the International Fresh-cut Produce Association developed and published industry guidelines on produce food safety (International Fresh-cut Produce Association, 1997).
In 1998, 2,288 became ill associated with 32 separate fresh produce outbreaks. In January, 1998, the New York Times ran a front-page article, along with several additional articles, highlighting produce food safety and noting the importance of on-farm strategies to reduce risk.

Beuchat (1998) noted that risk management strategies for fresh produce were difficult because potential pathogen sources in fresh fruit and vegetable production were numerous, and irrigation water containing raw sewage or improperly treated effluents from sewage treatment plants may contain hepatitis A, Norwalk viruses, or enteroviruses in addition to bacterial pathogens such as *E. coli* O157:H7, *Salmonella* spp. and *Shigella* spp.

In 1999, several more outbreaks of Shiga-toxin producing *E. coli* (STEC) were linked to leafy greens (Table 2), and the U.S. group, the United Fresh Fruit and Vegetable Association, developed and published HACCP-based food safety guidelines for the industry (United Fresh Fruit and Vegetable Association, 1999).

**Table 2 here**

Rafferty and others (2000) demonstrated that *E. coli* could spread in plant production cuttings from one contaminated source,
magnifying an outbreak to a whole farm. A 2001 outbreak of Shigella flexneri (886 ill) in tomatoes (Reller and others, 2006) further focused public and scientific attention on fresh produce.

Solomon and others (2002a) discovered that the transmission of E. coli O157:H7 to lettuce was possible through both spray and drip irrigation. They also found that the pathogen persisted on the plants for 20 days following inoculation and submerging the lettuce in a solution of 200 ppm chlorine did not eliminate all viable E.coli O157:H7 cells, suggesting that irrigation water of unknown microbial quality should be avoided in lettuce production (Solomon and others, 2002a). In a follow-up experiment, Solomon and others (2002b) explored the transmission of E. coli O157:H7 from manure-contaminated soil and irrigation water to lettuce plants. The researchers recovered viable cells from the inner tissues of the lettuce plants and found that the cells migrated to internal locations in plant tissue and were thus protected from the action of sanitizing agents. These experiments demonstrated that E. coli O157:H7 could enter the lettuce plant through the root system and migrate throughout the edible portion of the plant (Solomon and others, 2002b). Such results were widely reported in the general media.

During this time, several outbreaks of E. coli were again linked to lettuce and salad (Table 3).
In 2003, according to Mexican growers, the market impact of an outbreak of hepatitis A traced to exported green onions lasted up to 4 months while prices fell 72% (Calvin and others, 2004). Roma tomatoes were identified as the source of a salmonellosis outbreak that resulted in over 560 cases in both Canada and the US (CDC, 2005).

During 2003-2005, several additional outbreaks of E. coli O157:H7 were linked to fresh leafy greens, including one multi-state outbreak involving Dole bagged lettuce (Table 4).

During 2005-2006, four large multistate outbreaks of Salmonella infections associated with eating raw tomatoes at restaurants occurred in the U.S., resulting in 459 culture-confirmed cases of salmonellosis in 21 states. Investigations determined that the tomatoes had been supplied to restaurants either whole or precut from tomato fields in Florida, Ohio, and Virginia (CDC, 2007).

Allwood and colleagues (2004) examined 40 items of fresh produce taken from a retail setting in the U.S. that had been
preprocessed (including cut, shredded, chopped or peeled) at or before the point of purchase. They found fecal contamination indicators (E. coli, F-specific coliphages, and noroviruses) were present in 48% of samples.

Researchers in Minnesota conducted a small-scale comparative study of organic versus conventionally grown produce. They found that while all samples were virtually free of pathogens, E. coli was 19 times more prevalent on produce acquired from the organic farms (Mukherjee and others, 2004). They estimated that this was due to the common use of manure aged for less than a year. The use of cattle manure was found to be of higher risk as E. coli was found 2.4 times more often on farms using it rather than other animal manures (Mukherjee and others, 2004).

$\textit{Industry efforts/regulation}$

The current state of risk-based food safety systems suggests that food producers follow HACCP-based programs, employing the strategy to its limits where applicable (U.S. National Advisory Committee on Microbiological Criteria for Foods Washington, 1999).

There are a variety of generic and specific guidelines for safe fresh fruit and vegetable production in North America. These programs are generally based on HACCP and many are also

It has been suggested that produce farmers follow risk-based guidelines. The U.S. National Advisory Committee on Microbiological Criteria for Foods (1999) suggests that while HACCP should be used, not enough is known about the vectors of contamination. Programs need to be flexible, but still based on what is known. They also suggest that a formal HACCP system is too rigid for the farm, but the principles can still be applied to reduce risk. Translating HACCP-based strategies to the farm has resulted in a set of generic guidelines described as good agricultural practices (GAPs) and include:

GAPs

• equipment maintenance program
• sanitation program within facilities/packing areas
• end of season cleaning
• washroom facilities
• employee training
• pest control program
• storage maintenance program
• transportation program
• microbiological sampling
In response to increasing outbreak investigation results pointing to lettuce and tomatoes as sources of foodborne illness, Dr. Robert Brackett of U.S. FDA/CFSAN issued a letter in February, 2004 to the entire lettuce and tomato supply chains expressing “serious concern,” and expectations of the industry to enhance the safety of their products (U.S. Food and Drug Administration, 2004), stating,

"Because fresh vegetables such as lettuce and tomatoes are commonly consumed in their raw state without processing to reduce or eliminate pathogens, the manner in which they are grown, harvested, sorted, packed, and distributed is crucial to ensuring that the potential for microbial contamination is minimized, thereby reducing the risk of illness to consumers.

In 1998, the FDA issued a "Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables," (available at http://www.foodsafety.gov/~dms/prodguid.html) which discusses recommended good agricultural practices (GAPs) and good manufacturing practices (GMPs) that growers, packers and shippers can undertake to address common risk factors in their operations and thereby, minimize food safety hazards potentially associated with fresh produce. We have worked in partnership with your industries in the U.S. and abroad since that time to promote our recommendations and to advance the scientific knowledge applicable to enhancing the safety of fresh fruits and vegetables.

In addition, in 2001, FDA made available a report prepared for the agency under contract by the Institute for Food Technologists, "Analysis and Evaluation of Preventive Control Measures for the
Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce," available at http://www.cfsan.fda.gov/~comm/ift3-toc.html. This report summarizes the current scientific research relating to the various methods of eliminating or reducing pathogens, while maintaining fresh attributes, on whole and fresh-cut produce.

In view of continuing outbreaks associated with fresh lettuce and fresh tomatoes, we strongly encourage firms in your industries to review their current operations in light of the agency's guidance for minimizing microbial food safety hazards in fresh lettuce and fresh tomatoes, as well as other available information regarding pathogen reduction or elimination on fresh produce. We further encourage these firms to consider modifying their operations accordingly, to ensure that they are taking the appropriate measures to provide a safe product to the consumer. Since the available information concerning some of the recent outbreaks does not definitively identify the point of origin of the contamination, we recommend that firms from the farm level through the distribution level undertake these steps.”

On Nov. 4, 2005, Dr. Brackett, wrote a second letter to California lettuce producers, packers and shippers, urging them to re-examine and modify operations from the farm through to distributors to ensure that consumers were provided with a safe product (U.S. Food and Drug Administration, 2005).

Dr. Brackett's November letter noted that FDA was aware of 18 outbreaks of foodborne illness since 1995 caused by *E. coli* O157:H7 in which fresh or fresh-cut lettuce was implicated as the outbreak vehicle. In one additional case, fresh-cut spinach was implicated. These 19 outbreaks accounted for 409 reported cases of illness and two deaths.
"In view of continuing outbreaks associated with fresh and fresh-cut lettuce and other leafy greens, particularly from California, we are issuing this second letter to reiterate our concerns and to strongly encourage firms in your industry to review their current operations in light of the agency's guidance for minimizing microbial food safety hazards in fresh fruits and vegetables, as well as other available information regarding the reduction or elimination of pathogens on fresh produce. We encourage firms to consider modifying their operations accordingly to ensure that they are taking the appropriate measures to provide a safe product to the consumer. We recommend that firms from the farm level through the distribution level undertake these steps."

and

"Foodborne illness investigations rarely pinpoint the point of origin of the contamination. However, claims that "we cannot take action until we know the cause" are unacceptable. We believe that there are actions that can and should be undertaken immediately to address this issue. For example, at least some outbreaks may be related to contamination that may have occurred in the production environment. In June 2004, the California Department of Health Services, Food and Drug Branch (CDHS-FDB) initiated multi-agency, collaborative research aimed at identifying the environmental reservoirs for E. coli O157:H7, and understanding how lettuce may become contaminated. In a preliminary report presented at the August 2005 annual meeting of the International Association for Food Protection, E. coli O157:H7 was isolated from sediment in an irrigation canal bordering a ranch that had been identified in three separate outbreaks. The ranch is bowl-shaped; it sits upon a drained lake, and is highly susceptible to localized flooding. Expanded sampling in the Santa Rita Creek and the Salinas Valley area indicate that creeks and rivers in the Salinas watershed are contaminated periodically with E. coli O157:H7. The specific source of contamination
that led to the outbreaks was not identified. However, several possible sources of contamination were identified, both on the ranch initially studied and upstream. Although it is unlikely that contamination in all 19 outbreaks was caused by flooding from agricultural water sources, we would like to take this opportunity to clarify that FDA considers ready to eat crops (such as lettuce) that have been in contact with flood waters to be adulterated due to potential exposure to sewage, animal waste, heavy metals, pathogenic microorganisms, or other contaminants. FDA is not aware of any method of reconditioning these crops that will provide a reasonable assurance of safety for human food use or otherwise bring them into compliance with the law. Therefore, FDA recommends that such crops be excluded from the human food supply and disposed of in a manner that ensures they do not contaminate unaffected crops during harvesting, storage, or distribution. Adulterated food may be subject to seizure under the Federal Food, Drug, and Cosmetic Act, and those responsible for its introduction or delivery for introduction into interstate commerce may be enjoined from continuing to do so or prosecuted for having done so.”

For retail and foodservice establishments, the U.S. FDA 2005 Model Food Code Section 3-302.15 specifies: "Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form." Packaged produce labeled “ready-to-eat,” “washed” or “triple washed” need not be washed.

In April 2006, Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain produced by International Fresh-cut Produce Association, the Produce
Marketing Association, United Fresh Fruit and Vegetable Growers, and Western Growers (2006), were published.

Whatever the preferred production and processing method may be for a single producer, the lettuce/leafy greens industry recognizes the following basic principles that serve as the foundation for all food safety programs found within the industry:

• The lettuce/leafy greens industry recognizes that once lettuce/leafy greens are contaminated, removing or killing pathogens is difficult. Therefore, prevention of microbial contamination at all steps from production to distribution is strongly favored over treatments to eliminate contamination after it has occurred.
• The lettuce/leafy greens industry supports implementation and documentation of food safety programs that utilize risk assessment techniques that identify significant risks and use a preventive approach to ensure safe food products.
• The lettuce/leafy greens industry also supports and encourages routine and regularly scheduled food safety awareness training for all persons who grow, handle, distribute, process, prepare and/or serve lettuce/leafy greens products.
• The human pathogens most often associated with produce (Salmonella and E. coli O157:H7) cause infection and illness by the fecal-oral route of food contamination. Therefore, lettuce/leafy greens food safety programs should pay special attention to controlling, reducing and eliminating potential fecal contamination from people and domestic and wild animals through the most likely conduits, that being human hands, water and soil.

What was absent in this decade of outbreaks, letters from regulators, and plans from industry associations and media accounts, was verification that farmers and others in the farm-to-fork food safety system were seriously adapting to the
messages about risk and the numbers of sick people, and then translating such information into behavioral changes that enhanced front-line food safety practices.

The 1996 outbreaks and the 1998 FDA guide did help initiate efforts to implement on-farm food safety programs. The very nature of produce that makes it healthy (fresh and consumed raw) is what makes fresh produce a high-risk food for transmitting microbial contamination. Without the microbiological kill step provided by cooking, produce is vulnerable to contamination from the farm-to-fork.

Pathogens can contaminate at any point along the food chain, at the farm, in the packing shed, processing plant, transportation vehicle, retail store or foodservice operation, and the home. By understanding where potential problems exist, it is possible to develop strategies to reduce risks of contamination (Tauxe, 1997). Consequently, methods of growing, handling, processing, packaging and distributing fresh produce have received increased attention in terms of identifying and minimizing microbiological hazards.

HACCP is a system of food safety control based on a systematic approach to the identification and assessment of hazards associated with food operations and the definition of means for their control. This approach focuses on prevention and control and is advocated at every stage in the food chain,
from primary producers through to the final consumer (California Strawberry Commission, 1998; International Fresh-cut Produce Association and Western Growers Association, 1997; United Fresh Fruit and Vegetable Association, U.S., 1997). The produce industry has focused on developing and implementing programs aimed at reducing foodborne disease and illness. Complete HACCP systems cannot be implemented in fresh produce operations, as there is no definite kill step, such as pasteurization. Instead, these HACCP-based systems help to identify and reduce the potential for microbial contamination along the entire production and distribution process. A successful program helps avoid recall campaigns, adverse publicity, loss of sales and serves to enhance public health. There is value in applying the steps of HACCP to fruit and vegetable production, using available scientific information as part of the framework, to reduce the risk of foodborne pathogens. All of this was known a decade before the "tipping point" outbreak of E. coli O157:H7 in spinach in the fall of 2006.

$\textbf{Spinach}$

On Sept. 14, 2006, FDA issued a public statement warning against the consumption of bagged fresh spinach. "Given the severity of this illness and the seriousness of the outbreak,“
stated Dr. Robert Brackett, Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), “FDA believes that a warning to consumers is needed,” (U.S. Food and Drug Administration, 2006i). That evening, Dr. David Acheson, head of the FDA/CFSAN, told the public, "The FDA is advising consumers not to eat bagged fresh spinach at this time and that any individuals who believe they may have experienced symptoms of illness associated with E. coli contact their health care provider,” (Pal, 2006). Dr. Brackett assured the public. “We are working closely with the U.S. Centers for Disease Control and Prevention (CDC) and state and local agencies to determine the cause and scope of the problem,” (Harris, 2006). According to the New York Times, when asked if consumers should also avoid bagged salads, Dr. Acheson answered, "At this point, there is nothing to implicate bagged salad,” (Harris, 2006).

Bill Marler, a Seattle lawyer specializing in foodborne illnesses, filed a lawsuit that day on behalf of Gwyn Wellborn, who became seriously ill after eating a bag of Dole baby spinach. "We are not pointing at a single source unambiguously," said Marler. "Dole is one of the companies on the radar," (Lynn, 2006). A spokesman for Washington State’s Department of Health was still saying, “Nobody wants to point fingers yet until they know they are pointing in the right direction” (Lin, 2006). Dr. William E. Keene, a senior epidemiologist for the Oregon Public
Health Division, told the Oregon Statesman-Journal, "We're sure that packaged spinach is the source of the outbreak. What we're not sure about is the brand" (Lynn, 2006).

By Sept. 15, 2006, state and local agencies issued advisories. "We're telling people if they have bagged produce and they feel like it's a risk, throw it out," said T.J. Bucholz, the spokesman of the Michigan Department of Community Health, "If they feel like they have to eat it, wash it first in warm water" (Pal, 2006). The Canadian Food Inspection Agency warned against fresh spinach imported from the U.S., describing the outbreak as sickening nearly 100 people, though no cases had been reported in Canada. "Washing the spinach won't make it safe," announced CBC News (2006), "because the E. coli sticks to the leaves tightly." This statement referred to Dr. Brackett’s message to the Associated Press (AP) that day when he said, "If you wash it, it is not going to get rid of it." The AP story also stated that federal and state health officials were trying to pinpoint a source of contamination in California, where the spinach was believed to have been grown (Bridges, 2006b). In another AP report, Dr. Acheson said health officials did not know of any link to a specific growing region, grower, brand or supplier. Amy Philpott, a spokeswoman for the United Fresh Produce Association, said, "Our industry is very concerned. We're taking this very seriously (Bridges, 2006a)."
David Brown (2006) of the Washington Post speculated, “Crops such as spinach could conceivably be contaminated by liquid fertilizer sprayed on fields,” because of the enteric nature of the bacterium.

Natural Selection Foods, LLC (2006), initiated a recall of all their products containing spinach with “Best if Used by Dates” of August 17th through October 1st after consulting with the FDA and the California Department of Health Services. “While neither the FDA nor the CDHS have yet determined the source of the E. coli problem, we believe that recalling all spinach product packed in our facilities is the right thing to do,” said Charles Sweat (2006) in a separate statement. “The FDA has said that they are looking at the entire industry and we will continue to do our part in their investigation.”

Tom Stenzel, President and CEO of the United Fresh Produce Association (2006), issued the statement, “The fresh produce industry commends the company for taking this pro-active action to ensure consumer health. While we understand that no definitive evidence has yet linked E. coli 0157:H7 to a specific spinach sample, we applaud the company for voluntarily recalling product to ensure the utmost caution in protecting health.” Stenzel also said on behalf of the Association, “We commend the FDA and industry for working together to first protect public health, and then isolate the cause of the outbreak in order to
help restore confidence in the overall spinach industry as quickly as possible.”

Later in the day, Natural Selection Foods was linked to the outbreak through an epidemiological study wherein victims recalled eating spinach sold by the company under several different brands. "We are very, very upset about this," said Natural Selection Foods spokeswoman Samantha Cabaluna. "What we do is produce food that we want to be healthy and safe for consumers, so this is a tragedy for us." The company offered refunds for spinach tossed out due to the recall, or coupons to buy new packages (Bridges, 2006c). Natural Selection Foods LLC halted shipments of all fresh spinach products and said in a statement that it was cooperating with federal and state health officials to identify the source of the contamination (Bridges, 2006d).

Kenter Canyon Farms, Inc. initiated a voluntary recall of re-packaged spinach that was not realized by FDA until recall audits were conducted in October (U.S. Food and Drug Administration, 2006g).

On Sept. 16, 2006, Dole Food Company, Inc. (2006) announced its support of the recall by Natural Selection Food LLC in a statement on Saturday, though Dole holds no economic interest in the firm. The statement also said, “Dole is committed to assisting the FDA, the California Department of Health Services
and other regulatory agencies in their investigations and this recall by Natural Selection Foods."

Earthbound Farm, the packaged brand of Natural Selection Foods produce, was still working with officials to determine the source of the contamination. "We're not even thinking about the cost right now," Earthbound spokeswoman Samantha Cabaluna said. "We're trying to do the right thing, to protect public health and get to the bottom of this." She also mentioned that it was unclear whether the organic or conventionally grown spinach was the cause of the outbreak (Robertson, 2006). By Sunday, Sept. 17, 2006, Earthbound Farm (2006) assured customers that none of their organic spinach had been directly connected with the illnesses at this point in the investigation. This statement came after concern arose that organic farming practices may have lead to contamination.

River Ranch, another California company, also recalled its spring mix containing spinach because it had received bulk spring mix containing spinach from Natural Selections (U.S. Food and Drug Administration, 2006j). Their spring mix was also sold under Hy-Vee, Fresh N’ Easy and Farmers Market labels (Norton, 2006).

The FDA decided to expand the Lettuce Safety Initiative to include 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,” said an FDA update on the spinach outbreak (2006b). By that time, a total of 109 cases had been linked to the outbreak, including 16 cases of Hemolytic Uremic Syndrome (HUS), and more were continually being reported to the CDC (U.S. Food and Drug Administration, 2006b). Columbus, Ohio, news station WBNS reported the death of 23-month-old Olivia Perkins from complications related to E. coli contraction (Black, 2006).

By Monday, Sept. 18, 2006, Caroline Smith DeWaal, director of food safety for the Center for Science in the Public Interest, was quoted as saying, "We think this incident shows the FDA is suffering from the same weak-kneed approach that they had before they were given more power to regulate beef in the 1990s. ... "No one is really in charge of food safety on the farm, and the FDA has come in with fairly weak guidelines there that they can only suggest but not enforce," (Wood, 2006).

On Wednesday, Sept. 20, 2006, the New Mexico Department of Health (2006) confirmed the presence of the outbreak strain of E. coli 0157:H7 in a bag of spinach belonging to a patient in the investigation using “DNA fingerprinting.” The spinach had been produced and packed conventionally at an Earthbound Farm facility. “This news confirms our decision to go out early with our voluntary recall,” said an Earthbound Farm Media Release
“Natural Selection Foods is a company built on doing the right thing. In this situation, protecting the public health even before we had much information was the right thing to do.”

On Sept. 24, 2006, the Utah Department of Health and the Salt Lake Valley Health Department had positively identified the outbreak strain in a bag of Dole baby spinach purchased in Utah (U.S. Food and Drug Administration, 2006c). By Sept. 26, 2006, FDA (2006d) stated, “FDA has determined that the spinach implicated in the outbreak was grown in three California counties: Monterey, San Benito, and Santa Clara. Spinach grown in the rest of the United States has not been implicated in the current E. coli O157:H7 outbreak. The public can be confident that spinach grown in the non-implicated areas can be consumed.” Additionally, the Pennsylvania Department of Health confirmed the presence of the outbreak strain in a bag of Dole baby spinach.

By Sept. 29, 2006, FDA (2006a) announced that “all spinach implicated in the current outbreak has traced back to Natural Selection Foods LLC of San Juan Buatista, California,” according to epidemiological investigations coordinated by the CDC at multiple state laboratories. The Grower Shipper Association of Central California, the Produce Marketing Association, the United Fresh Produce Association, and the Western Growers
Association, said, "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." The FDA commented, "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."

Also at this time, the Colorado Department of Public Health and Environment, the Ohio Department of Health, and the Nevada Department of Health and Human Services confirmed the presence of the outbreak in a samples of Dole spinach, and the Wisconsin Department of Health and Family Services confirmed its presence in two bags of Dole Baby Spinach. The Pennsylvania Department of Health found a second bag of Dole spinach containing the outbreak strain. On Oct. 4, 2006, the Arizona Department of Health Services found the outbreak strain in a bag of Dole spinach (U.S. Food Drug Administration, 2006e).

U.S. Attorney Kevin V. Ryan simultaneously issued search
warrants on Growers Express and Natural Selection Foods (U.S. Food and Drug Administration, 2006f).

An Oct. 5, 2006, letter from Earthbound Farm co-founders, Drew and Myra Goodman stated, “While our food safety systems have always been at the top of the industry, this outbreak has demonstrated the immediate need for improved industry protocols.” The letter went on to describe the new safety measures now in place at the company’s growing and processing facilities (Goodman, 2006).

On October 12, 2006, FDA and the state of California announced that samples of cattle feces had tested positive for the outbreak strain of E. coli. Infected cattle feces were found on one of four fields implicated by a trace back investigation (U.S. Food and Drug Administration, 2006h). "This is a significant finding because it is the first time we linked a spinach or lettuce E. coli O157:H7 outbreak to test results from a specific ranch in the Salinas Valley," said California State Public Health Officer Dr. Mark Horton (California Department of Health Services Media Release, 2006).

$\textit{a}$ Summary

Following the September 2006 E. coli O157:H7 outbreak linked to Natural Selections Foods, the California Food Emergency Response Team (CalFERT) conducted an investigation of
the spinach supply chain (including growing conditions, harvesting, washing and packaging). Investigators observed conditions and collected finished product and environmental samples. CalFERT investigators found no *E. coli* O157:H7 at the processing site, and reported that: "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." CalFERT investigators reported that *E. coli* O157:H7 was discovered in environmental samples taken from near each of the four fields linked to the outbreak-linked product codes. CalFERT investigators also reported that only one of the sampled fields produced *E. coli* O157:H7 isolates that matched the outbreak strain. These matching samples were taken from river water, cattle feces and wild pig feces. Investigators reportedly found evidence of wild pigs amongst cattle pastures as well as in the spinach production fields. It was also found that there was a lack of fencing to keep wild animals such as pigs out of fields and that a well used for irrigation had a damaged casing. CalFERT investigators reported that a small amount of land on this site was leased to Mission Organics for a transitional ready-to-eat organic spinach product. The product was being grown to organic standards but was being sold as conventional during a three year
transition period. Ultimately, investigators showed that the *E. coli* O157:H7 was found on a transitional organic spinach field and was the same serotype as that found in a neighboring grass-fed cow-calf operation.

These findings, coupled with the public outcry linked to the outbreak and the media coverage, sparked a myriad of changes and initiatives by the industry, government and others. What may never be answered is, why this outbreak at this time? A decade of evidence existed highlighting problems with fresh produce, warning letters were written, yet little was seemingly accomplished. The real challenge for food safety professionals, is to garner support for safe food practices in the absence of an outbreak, to create a culture that values microbiologically safe food from farm-to-fork at all times, and not just in response to the glare of the media spotlight.
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