Unfinished Business: Preventing *E. Coli* O157 Outbreaks in Leafy Greens

by Charles Benbrook, Ph.D.
Chief Scientist
The Organic Center

June 2007

Table of Contents

Executive Summary

Much more than the fate of the multi-billion dollar fresh leafy greens industry is at stake in the wake of last fall's *E. coli* O157:H7 outbreak. Why? Because increasing daily consumption of fresh fruits and vegetables is an essential first step in improving the health of the average American.

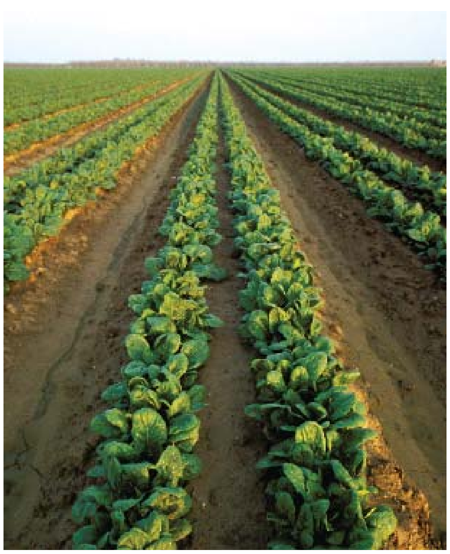
The health promoting potential of fresh produce is why the government has recently recommended a big increase in daily fruit and vegetable consumption, from five servings a day to eight to 13, depending on an individual's size and activity level.

Any factor that erodes confidence in the safety of fresh produce will undermine ongoing efforts to increase consumption. The next high-visibility outbreak, whether triggered by spinach from California, melons from Mexico, green onions from a large conventional farm, or organic radicchio bought at a farmers market, will further erode consumer confidence in the safety of fresh produce.

New Food Safety Initiatives

Since last fall's outbreak, everyone involved in the growing, processing, and marketing of fresh leafy greens has been focused on how to prevent another outbreak. The good news is that growers and processors, especially in California, have adopted significant, new prevention-based food safety practices. A set of "Good Agricultural Practice (GAP) Metrics" for leafy green growers and processors has been developed by a coalition of industry and farm organizations.

Fresh Express, a major lettuce and spinach processor, has recently provided $2 million to fund nine studies focusing on the prevention of *E. coli* O157 in leafy greens. Projects are focusing on the ability of *E. coli* O157 to become internalized in lettuce and spinach; the possible role of insects in transmitting pathogens; and, environmental factors increasing the risk of extended survival or regrowth of foodborne pathogens.

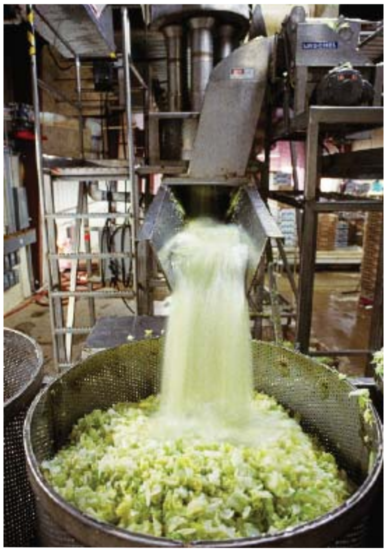


Natural Selection Foods (NSF), which is best known for its Earthbound Farm produce, processed the Dole brand baby spinach on August 15th that triggered the 2006 outbreak. The company's cooling, washing, and bagging procedures came under intense scrutiny as state and federal investigators searched for the cause of the outbreak. The effort to find where and how the *E. coli* O157 got into the raw spinach in the field was equally intensive and went on for over six months.

Within weeks of the outbreak and its own investigation of the outbreak, NSF decided to significantly augment its already strict food safety procedures, both in the plant and out in the field.

Testing of production inputs for pathogens was greatly expanded, and now encompasses seeds, irrigation water, composts and other soil amendments. All water used in the production process is tested weekly to monthly for enterohaemorrhagic *E. coli* and Salmonella. The environmental conditions in and around fields are assessed to identify – and avoid – possible sources of contamination. More, and more in depth field audits are routinely performed.

There were even more significant changes in NSF processing plant procedures. In the fall of 2006, two "firewalls" were added to their food safety system – the first "test and hold" firewall applies to raw product as it enters the plant, the second after product is washed, bagged and ready to ship. NSF now tests all incoming loads of raw product for enterohaemorrhagic *E. coli* (including O157:H7) and Salmonella, and holds the greens until the results confirm the absence of pathogens. Thus far, pathogens have been found in about three-dozen lots of raw produce, representing about one-tenth of one percent of the total pounds of raw product tested. These lots have been destroyed.



Leafty greens are washed three times in most processing plants.

A second firewall is in place, focused on fully processed and packaged product that is ready to ship. Samples from all lots are tested and held, and shipped only after results confirm the absence of pathogens. Thus far, no lots of finished product have tested positive, evidence that the dual-firewall approach is working.

The scope of foodborne pathogen problems, however, remains sobering, as does what it will take across the industry to prevent future outbreaks. Over 25,000 illnesses were triggered by *E. coli* O157:H7 in food in 2006, based on the most recent government data (see the box "The Challenge"). The spinach outbreak accounted for less than one-half of one percent of these cases, and about four percent of the illnesses likely triggered by *E. coli* in fresh produce.

Moreover, *E. coli* O157:H7 is not the only serious foodborne pathogen causing illness from consumption of fruits and vegetables. Three other strains of enterohaemorrhagic *E. coli* cause tens of thousands of cases each year. Salmonella causes many more cases than all strains of *E. coli* combined, but fewer cases leading to serious, life-threatening complications. Because of the significant health risks posed by *E. coli* and Salmonella infections and the upward trend in illnesses linked to fresh produce, these bacteria must become, at least in the near term, the dominant focus of monitoring and prevention efforts throughout the fresh cut industry.

Photo credit: Earthbound Farm

A worker takes a sample from a harvest machine to test for the presence of human pathogens. Everything that comes in contact with raw leafy greens must be carefully cleaned and continuously monitored.

The Challenge

The fall 2006 spinach outbreak led, according to the FDA, to 204 illnesses. The California Department of Health Services recently reported, however, that only 162 of the individuals that suffered illnesses reported eating spinach, and 151 reported eating bagged spinach. While most of the spinach that was found to contain the outbreak strain of *E. coli* O157 was Dole spinach, other brands were implicated in the outbreak. For many cases, the brand was not known.

Given the national press attention devoted to the fall outbreak, one would think it accounted for a significant share of last year's *E. coli* O157 illnesses. Not true.

Based on the most recent FoodNet data, about 52,000 cases of *E. coli* O157 illnesses were expected in 2006 (down 29% from 73,000 cases in 1999). CDC attributes this encouraging reduction in cases since 1999 to progress in reducing illnesses caused by undercooked hamburger. (Some articles report an estimated 100,000 cases of *E. coli* human illnesses annually, also citing data from the CDC. This larger number reflects the cases caused by four enterohaemorrhagic strains of *E. coli* , including O157:H7).

The 2006 spinach outbreak therefore accounts for less than one-half of one percent of the 52,000 illnesses expected in 2006 from all sources of exposure to *E. coli* O157.

Foodborne sources of *E. coli* O157 likely accounted for about 50 percent of the total number of outbreaks in 2006 and one-half the cases, or about 26,000, based on a CDC epidemiological study (Rangel et al., 2005). Produce (mostly lettuce and salads) accounted for an estimated 21% of outbreaks linked to foodborne transmission, or 5,460 cases.

The 204 cases triggered by the 2006 spinach outbreak thus represent fewer than 4 percent of the total number of produce-triggered cases.

This problem is far larger than most people realize and fresh cut produce from the Salinas Valley accounts for just a small share of it. Reducing *E. coli* O157 illnesses linked to produce is a national challenge that must be attacked systematically, every day, wherever fruits and vegetables are grown and processed.

Essential Ingredients in Widening Margins of Safety

The fastest way to substantially broaden fresh produce and leafy green margins of food safety will depend on a systematic, farm to fork approach. Success will depend on progress in three areas:

Reduce Pathogen Loads

A promising way to reduce the millions of human illnesses triggered annually by foodborne pathogens is to track the pathogens to their source, understand the conditions in which they thrive, and change those conditions. This approach is logical and proven, yet in the case of *E. coli* and leafy greens, is barely on the radar screen of industry leaders or government regulators.

A mountain of data and experience with foodborne illness outbreaks linked to fresh produce points to proximity of production fields to dairy and beef cattle operations – and manure – as a significant risk factor for *E. coli* O157 contamination.

Cattle and crop farming have co-existed on the same farms, and in the same regions for hundreds of years with few *E. coli* O157 illnesses linked to consumption of crops. But leafy greens marketed as ready-to-eat, fresh cut product are uniquely vulnerable to foodborne pathogens because:

- The harvested portion of the plants grow very close to the soil,
- The produce is not cooked, and
- The bags or clamshells containing fresh cut greens provide an excellent environment for bacterial proliferation,

if bacteria survive the washing and sanitation procedures, especially if the cold chain is broken or when consumers do not respect the product expiration date.

The unique vulnerability of fresh cut leafy greens to *E. coli* and Salmonella calls for added measures to keep cattle, and their manure well away from production fields.

Monitor, Study and Probe for Answers

More testing, and more accurate test methods are needed. *E. coli* O157 and Salmonella should be routinely tracked, rather than generic *E. coli* as now the case in the water testing provisions within the GAP Metrics.

The GAP Metrics total reliance on generic *E. coli* water testing is a serious flaw and should be rejected by growers, buyers, and the government. Innovative companies are already testing – and benefiting from – water and product testing protocols focusing on *E. coli* O157, other pathogenic forms of *E. coli* , and Salmonella. The industry has promised consumers that it will do everything possible to assure product safety. "Everything possible" surely must encompass routine testing of water and product for *E. coli* O157, other enterohaemorrhagic *E. coli*, and Salmonella.

Spinach samples are routinely collected in the field for testing.

The results of testing across farms, processors, and regions, whether done by individual farmers and processors, regulators, or researchers, need to be shared and analyzed by teams of experts so that new insights of value to everyone will emerge as quickly as possible.

The government can and should play a supportive role by offering financial support for testing, as long as accurate and verified methods are used and results pooled in a way that will allow researchers access to the broadest possible pool of test results.

Identify and Deal with High-Risk Circumstances

Moderate and high-risk fields need to be identified, based on past records of the sources of contaminated product and ongoing raw product testing programs.

In particular, fields within one-half mile of cattle operations or open range should ideally be planted to other crops for the next few years as science sharpens understanding of the causes of O157 outbreaks. If such fields are used for fresh cut leafy greens, the raw product harvested from the fields should be processed only in conjunction with a raw product and finished-product testing program encompassing all pathogenic strains of E. coli and Salmonella.

The combination of cattle and flood conditions can create a "perfect storm" for nearby vegetable growers.

Levels of risk associated with different sources of irrigation water will vary by orders of magnitude. It makes no sense to force growers to continue testing very clean water sources as frequently as those sources known to periodically bear possibly risky pathogen loads.

Relative risks associated with agronomic and pest control practices, and production inputs need to be assessed and communicated to growers. Those practices and inputs known to open the door to pathogens, or to encourage their growth, need to be flagged and matched with more intensive sampling and testing.

Tilting the Odds Against *E. coli* O157

Sprinkler irrigation systems are more efficient than furrow, or surface irrigation in transferring *E. coli* from water to growing plants. Over 90 percent of the spinach plants were contaminated with *E. coli* O157 after being irrigated with a sprinkler system, and water spiked with *E. coli*, compared to less than 20 percent of the plants under surface irrigation (Solomon et al., 2002a). Sprinkler systems result in more splashing onto leaf surfaces of a mixture of soil and water.

Management practices that support the establishment of diverse microbial communities on the leaf surface can slow or block the proliferation of *E. coli* O157 (Aruscavage et al., 2006). The lack of fungicide use in organic production systems and reliance on composts and other soil amendments that support microbial biodiversity can help place *E. coli* O157 bacteria at a competitive disadvantage. The generally higher levels of phytochemicals expressed by plants grown in organic systems can also lead to direct suppression of *E. coli* O157 (Dingman, 2000).

Plant defense mechanisms can also reduce the odds of *E. coli* O157 proliferation (Suslow et al., 2003). Healthy plants have been shown to ward themselves of E. coli infections within days to a few weeks after infections. The possible mechanisms leading to this outcome include the production of phytochemicals with anti-bacterial activity and stimulation of a plant's defenses through a process known as systemic acquired resistance (Aruscavage et al., 2006; Suslow et al., 2003).

Pathogenic bacteria that find their way to crop fields need a source of energy to proliferate. Excessive levels of nitrogen fertilizer in a field are known to increase the plant's release of nitrogen compounds both through the root system and the leaf surface, possibly stimulating bacterial growth (Aruscavage et al., 2006). Nitrogen is typically released more slowly in organic production systems, a factor that may emerge as a food safety advantage.

Practices and inputs known to be helpful in preventing initial pathogen colonization in a field, or capable of suppressing pathogen growth, also need to be identified and incorporated in production systems to the extent possible.

Some options are described in the box "Tilting the Odds Against *E. coli* O157," and include promoting microbial biodiversity, healthy plant defense mechanisms, and avoiding excessive levels of nitrogen in soils, which can stimulate plants to produce exudates that can stimulate *E. coli* O157 and Salmonella proliferation.

Throughout the 2007 production season, growers and processors must err on the side of excessive caution. They need to test for pathogens at more places, more frequently. The data generated will hopefully soon point to high-risk fields and practices, as well as fields and systems that pose little if any risks.

Only the highest quality production inputs should be used, especially composts and other soil amendments made from manure or other animal byproducts. Adherence to manufacturing and process standards should not be relied on exclusively to assure that soil amendments are safe for use in fresh cut leafy green production. These important production inputs should be tested routinely through the 2007 season to assure that, for example, finished compost is really finished and stable, and pathogen free, and remains so until incorporated into the soil in a production field. Compost manufacturers should not be expected to shoulder the full cost of the intensified testing that is necessary for the next few years.

Internal inconsistencies and gaps in the soil amendment provisions in the GAP Metrics should be addressed in time to guide compost manufacturers this fall, as they produce the compost that will be used early in the 2008 production season. If stricter, more science-based compost standards are not incorporated in the GAP Metrics by the fall of 2007, organic growers and certifiers should work together to develop additional compost quality standards that can be put in place quickly, so that organic farmers will be able to purchase compost in 2008 that is fully finished and meets the strict pathogen standards now in the GAP Metrics.

Moving Forward

From farm to fork, multiple and redundant prevention-based practices should be implemented. And at each step along the way, testing should be relied on to check whether prevention-based interventions are working and to identify high-risk circumstances in need of special attention.

More sensitive and specific test methods should be adopted. This step will help assure an outbreak-free 2007 season, and should also generate critical new knowledge needed to chip away at the 52,000 cases of human illness traced to *E. coli* O157 in recent years.

Photo credit: Earthbound Farm

Leafy greens in the first wash cycle at the National Selection Foods, San Juan Bautiste plant.

Valuable new food safety measures pioneered and proven by one company should be quickly adopted industry-wide. In particular, the testing-based firewalls implemented by NSF appear to be working as intended, and are clearly affordable for any major processing plant.

Pursuing these and other new strategies can expand fresh leafy green margins of safety significantly and quickly, and without driving up production costs to the point where no farmer or processor can stay in business.

This is fortunate, since farms in California now account for a significant share of the daily consumption of fresh fruits and vegetables for many Americans during several months each year. If fresh leafy greens were no longer grown in California, imports would surge, no doubt bringing along with them another set of food safety challenges and outbreaks. Before long, trust in produce safety will decline enough to depress the average number of daily servings and in turn, our collective public health.

This is why the stakes are so high this summer. Progress has clearly been made through coordinated efforts within the industry, and individual companies have raised the food safety bar.

Thus far, the government has been a passive observer of events and has done little to support innovation, punish those who cut corners, and spread the costs required to widen margins of safety. This is unfortunate since more can and should be done to develop and fully implement strategies that will reliably drive down *E. coli* O157 and other foodborne pathogen risks to as close to zero as possible, as quickly as possible.

The 2006 *E. coli* O157 Outbreak: Possible Causes and Lessons Learned (and Relearned)

According to Food and Drug Administration (FDA) updates and fact sheets, the outbreak of illnesses linked to *E. coli* O157:H7 in the summer and fall of 2006 triggered 204 known cases, 31 cases involving the serious complication Hemolytic Uremic Syndrome (HUS), 104 hospitalizations, and three deaths. Illnesses occurred in 26 states. The FDA first became aware of the outbreak on September 13, 2006, although the first illness connected to the outbreak began on August 2, 2006.

In the last two weeks of September and into late October, the Centers for Disease Control (CDC) and FDA produced sometimes-daily updates of the number of cases. On September 17th, an update from FDA reported 109 cases in 19 states, and restated advice to consumers to not eat products containing fresh spinach, regardless of the source. At this point, no information was publicly available regarding the spinach products that triggered the outbreak.

The FDA's September 26, 2006 statement reported 183 cases in 26 states, and one death. An outbreak case in Pennsylvania was linked to a bag of Dole baby spinach that contained the same strain of *E. coli*. Over the next two weeks, several other outbreak cases were linked to consumption of Dole brand baby spinach packed under contract by Natural Selection Foods (NSF), a company that does business as Earthbound Farm.

Throughout the fall of 2006 and into 2007, the FDA and the California Department of Health Services carried out a mammoth investigation of the outbreak. The long-awaited final report of the "California Food Emergency Response Team" was issued March 21, 2007, and was entitled "Investigation of an *Escherichia coli* O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach." The report's Executive Summary included several key findings and conclusions:

- None of the samples of water, raw spinach, or finished product from the San Juan Bautista plant where the Dole spinach was processed tested positive for *E. coli* O157:H7.
- Conditions were observed in the processing plant that "may have provided opportunities for the spread of pathogens, if pathogens arrived on incoming spinach."
- Several outbreak cases were traced to raw product processed during shift A on August 15, 2006; Natural Selection Foods records showed that spinach grown on four fields in Monterey and San Benito counties were processed during that shift.
- *E. coli* O157 was found in environmental samples collected near each of the four fields, but the exact strain associated with the outbreak was found only near the field located on the Paicines Ranch.
- The outbreak strain of O157 was found in river water, cattle feces, and wild pig feces on the Paicines Ranch, and within one mile of the spinach production field processed on August 15th.
- The field implicated in the outbreak was leased to Mission Organics and was undergoing transition from conventional to organic production.

- The presence of wild pigs in and around the spinach fields, and the proximity of cattle feces to surface waters and wells used for irrigation were identified as potential environmental risk factors.

Despite the intensity of the investigation, the Response Team ended its summary by stating:

"No definitive determination could be made regarding how *E. coli* O157:H7 pathogens contaminated spinach in this outbreak."

Location and Possible Causes of the 2006 Spinach Outbreak

Two of the four fields that the Response Team focused on during its investigation are located in relatively narrow valleys a few miles away from the main portion of the Salinas Valley - see the photographs in this section.

Photo credit: Ed Young

The Salinas River winds through the valley. Portions of fields along the river are periodically flooded, a risk factor for pathogen problems.

Cattle pasture and rangeland, and areas supporting deer and feral pigs, border spinach production fields on these two ranches. In the area around the Paicines Ranch, intermittent streams and a small river flows through the bottom of valleys, often adjacent to intensively farmed, high value cropland (see pictures). Several ponds and small reservoirs are located throughout the secondary valleys, sometimes adjacent to fields producing fresh produce. The ponds and reservoirs are typically used for irrigation or watering livestock, and sometimes both.

While there are few cattle in and around the heart of the Salinas Valley, grazing livestock operations are common all around the edges of the valley, throughout the hills dividing the Salinas Valley

Photo credit: Ed Young

Wildland, cattle pastures, and intensively farmed vegetable fields co-exist throughout coastal California.

from nearby, secondary valleys, and in the hilly ground surrounding the secondary valleys (see photos).

Two, and possibly three food safety failures triggered the 2006 outbreak. The first failure occurred in the field - the movement of *E. coli* O157:H7 onto a leafy green production field in sufficient numbers to persist throughout the growing season.

A second failure may, or may not have occurred and entails the harvest operation. If the source of the contamination was feces from feral pigs, it is possible that the harvest crew missed signs indicating that wild pigs had been in the field (e.g., feces, tracks, crop damaged by feeding).

The processing plant's washing procedures also clearly failed to eliminate the *E. coli* O157 bacteria that entered the plant on the contaminated spinach, nor did the plant's quality assurance procedures detect the O157 bacteria in finished product.

Photo credit: K. L. Benbrook

Cattle grazing in January 2007, in close proximity to the outbreak field on the Paicines Ranch.

Field Contamination

While the precise cause of the September 2006 outbreak remains unknown, the most likely source of the *E. coli* O157 bacteria that found their way to the spinach field was the cattle grazing on and around the Paicines Ranch. The spinach production field on the Ranch is bordered to the north by a large cattle pasture and open grazing land, all of which slopes upward from the spinach field.

Cattle manure is deposited on this pasture during the winter-spring grazing period, some of which was likely contaminated with *E. coli* O157. Spring rains and runoff could have flushed some manure and bacteria down onto the nearby crop fields. Given the ability of *E. coli* O157 to persist for three or more months in the soil (Aruscavage et al., 2006), contamination via spring runoff is clearly a plausible cause of the outbreak.

The presence of cattle on the Paicines Ranch could have triggered the outbreak in another way. It is known that dust can carry viable *E. coli* O157 bacteria relatively long distances. Summers in and around the Salinas Valley are typically dry and warm, and sometimes hot. It is probable that some areas where cattle had aggregated in the winter and spring - around a source of drinking water, or near feed bunks or corrals, for example - would have a layer of dried manure on the surface of the ground. If such areas were disturbed during the hot part of the summer, either by animals, periodic mowing, horse trails, or farm equipment, dust would be stirred up and could have been blown over onto the actively growing spinach field.

During the hot portion of the season, irrigation water would likely be applied daily, or every other day via a sprinkler system, creating a perfect storm for O157 colonization - water to help adhere the dust to the growing leaves, coupled with moisture and heat to trigger bacterial proliferation.

The Response Team addresses in great detail several possible ways that *E. coli* O157 bacteria could have moved from the cattle pasture and rangelands to the spinach field - irrigation water, feral pigs, deer. But the fact remains that it was probably the cows in the area that were the source of the *E. coli*.

Indeed, several outbreaks traced to produce have occurred in areas where fresh fruits and vegetables are grown in close proximity to beef or dairy cattle. Runoff contaminated with manure from a dairy farm was identified by FDA as the likely source of the *E. coli* O157 in lettuce that triggered 81 illnesses in the Taco John outbreak in November-December 2006 (for details, see http://www.fda.gov/bbs/topics/NEWS/2007/NEW01546.html).

Wildlife is a possible, but unlikely source of field contamination with *E. coli* O157. A feral pig found near the Paicines Ranch contained the outbreak strain, as did pig feces in the surrounding area. While transmission by feral pigs is possible, it is not likely the cause of the 2006 outbreak, which obviously entailed a high level of contamination of hundreds, if not thousands of pounds of raw product. If feral pigs had spent enough time in the field to feed on, and defecate around such a large area of spinach plants, it is hard to imagine how the harvest crew could have missed evidence of feeding damage as harvest operations progressed.

Deer and wild geese, and other animals, can sometimes carry O157 bacteria, and can move the bacteria around an ecosystem. Still, dozens of published studies focusing on the potential role of wildlife in the spread of *E. coli* O157 reach the same conclusions – wildlife play a very limited, if any role in the epidemiology of *E. coli* O157 infestations in agricultural ecosystems.

Failure at the Processing Plant

The scope of the outbreak led FDA and CDC investigators to conclude early on that the outbreak was likely caused by a contamination episode in the field. Almost certainly, contaminated raw spinach entered the plant, and during Shift A on August 15th, the washing and hygienic measures in place were unable to fully cleanse the final, packaged product.

There are many possible explanations of what happened during Shift A that opened the door to viable O157 bacteria in finished product:

- *E. coli* O157 levels were unusually elevated in some raw product and overwhelmed the system's ability to control all bacteria;
- The system malfunctioned because of either mechanical or human error;
- Some O157 bacteria had moved systemically up into the leaf tissues, and were not reached by the wash water; or
- There was something unusual about the way the *E. coli* O157 was lodged on the leaf surfaces, because of the presence of a biofilm, or because the physical state of the leaves somewhere protected portions of leaf surfaces from the wash (e.g., leaves could have been folded, or stuck together).

Photo credit: Ed Young

Natural Selection Foods processing plant in San Juan Bautiste, California.

While some university research studies have demonstrated systemic movement of E. coli O157 up into plants via root systems (Aruscavage et al., 2006; Solomon et al., 2002b; Warriner et al., 2003a; Warriner et al., 2003b), this has never been documented in the field. Some of the studies that have demonstrated systemic movement into plants have also shown that the plant's defense mechanisms have been able to attack and eliminate the bacteria within days or a few weeks.

It is unlikely that definitive proof will emerge supporting one or more of the above possible explanations of what happened in the processing plant. Clearly though, something went wrong, with tragic and enormous consequences.

The inability of Natural Selection Foods to discover the cause of the outbreak, nor why its sanitation procedures failed, was a principle factor leading the company to augment its food safety protocols with a raw and finished product "test and hold" program.

Lessons Learned and Relearned

When one grower or processor has a food safety problem, all growers and processors will be impacted.

Preventing food safety problems in the field poses basically the same challenges for conventional and organic farmers.

Quick and accurate tracing of outbreaks to their source is necessary to limit the collateral damage triggered when product recalls are overly broad and needlessly protracted.

Outbreaks can happen despite no known lapse in "Good Agricultural Practices" or sanitary processing methods.

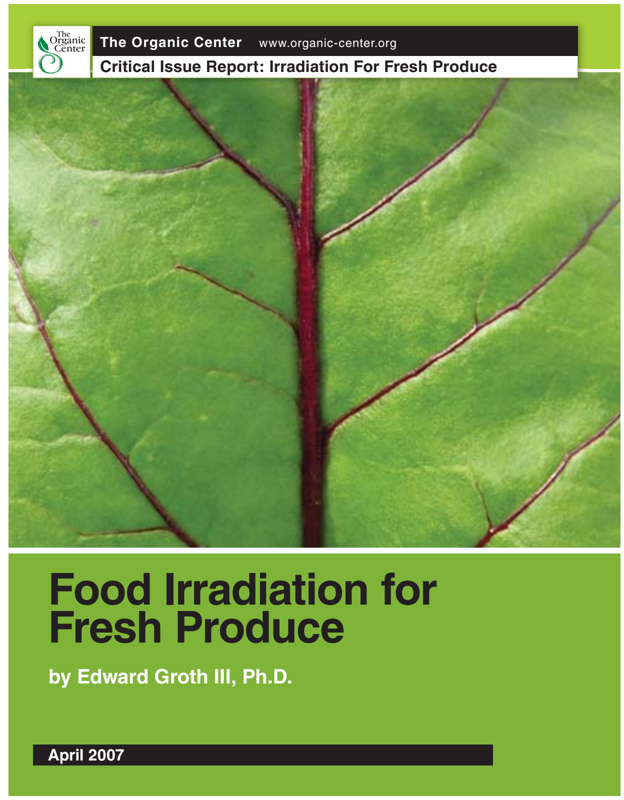
E. coli O157 bacteria are present periodically in cow manure, soil, water, and wildlife in and around the Salinas Valley, and every other valley in California and the U.S. Completely eliminating these bacteria is not feasible and attempts to do so would have devastating consequences.

Traceback systems work and are valuable in responding to an outbreak, determining its scope, and tracing the contamination to its source.

Quick-tests for generic *E. coli* sometimes produce false positives, which can severely tarnish the reputation of growers and processors, lead to unnecessary condemnation of safe product, and erode public confidence in fresh produce food safety. Pathogen-specific tests are more accurate and reliable, and should be relied on in prevention-directed testing and in the course of investigating future outbreaks.

More attention must be directed to improving the quality and reliability of foodborne pathogen testing methods. In particular, there is currently over reliance on generic *E. coli* and fecal coliform tests, and inadequate testing for *E. coli* O157 and Salmonella both in terms of frequency and sensitivity.

Each outbreak leads to renewed calls for the adoption of technologies and solutions that are promoted as "ready to go" and "highly effective," but which are neither. Irradiation of fresh cut produce is a good example (see the box "Is Irradiation of Fresh Cut Produce the Answer?")



Is Irradiation of Fresh Cut Produce the Answer?

No, for a host of reasons that are explained in the May 2007 Organic Center report by Dr. Edward Groth entitled "Food Irradiation for Fresh Produce." (Access the report at http://www.organic-center.org, under "State of Science," and "Food Safety").

In irradiating fresh produce, there are unresolved efficacy and food safety issues. Doses of radiation high enough to assure leafy green product safety will adversely and significantly impact product quality. Irradiation kills bacteria, but does not inactivate the potent toxins secreted by bacteria such as *Staphylococcus aureus* and *Clostridium botulinum*. These toxins can cause serious illness, even death, in the absence of any bacteria.

Irradiation can lead to the formation of possibly toxic chemical compounds, creating a new area of risk that will require in depth assessment. Many other technical questions remain about the safety of the process, efficacy, costs, and consumer acceptance.

Those advocating irradiation as "ready to go" are offering farmers, the food industry, and consumers a false promise that serves to distract attention from more immediate and proven solutions.

The GAP Metrics

The 2006 spinach outbreak was a seismic event across the fruit and vegetable industries. It cost growers millions of dollars in lost sales, raised new doubts in the minds of consumers about produce safety, and triggered strong criticism of the Food and Drug Administration (FDA) for lack of action, despite dozens of outbreaks from produce in recent years.

In response, the fresh cut industry accelerated work on a set of leafy green "Good Agricultural Practices" (GAP), now called the "GAP Metrics." The Western Growers Association (WGA) led the coalition of industry and farm groups developing the GAP Metrics. A committee of food safety experts was convened and dozens of meetings were held. The first draft of the Metrics circulated for comments in November 2006. A third draft was posted on the WGA website in late January 2007, and subsequent drafts were issued on April 18th and March 23rd, 2007.

The industry and WGA deserves credit for compiling a comprehensive and thoughtful set of "good agricultural practices" designed to promote leafy green food safety. Some problems with earlier drafts of the Metrics have been resolved, or at least minimized. In particular, several provisions in early drafts could have led growers to back away from soil and water quality practices and systems.

The emphasis on creating distance and barriers between leafy green fields and wildlife seemed to call into question the wisdom of planting riparian areas and field edges with diverse species of grasses and shrubs. Such plantings have been encouraged by government conservation agencies, are known to improve water quality, and attract and sustain populations of beneficial insects, including pollinators. Recent research carried out by specialists at the University of California-Davis has demonstrated the effectiveness of field edge and riparian plantings in filtering human pathogens out of surface runoff.

The industry also worked with the California Department of Food and Agriculture to set up a voluntary marketing agreement that would, among other things, require adherence to the GAP Metrics. The agreement establishes a governing board to oversee implementation of the agreement; it provides for the collection of fees; and, the right to use a seal indicating produce was grown in accord with recommended GAPs. A final draft of the Metrics, dated May 24, 2007, was prepared for adoption by governing body of the leafy greens marketing agreement.

A Work in Progress

According to the Western Growers Association, the GAP Metrics remain a work in progress. Refinements and additions will be adopted as new and better information emerges. The need for more and better science is also acknowledged at several places in GAP Metrics documents.

This is fortunate, since the GAP Metrics are incomplete and in some ways, seriously flawed. In evaluating the adequacy of the Metrics, the key question is --

"If the proposed GAP Metrics had been followed on outbreak fields, would past outbreaks have been prevented?"

The Organic Center provided detailed comments on the March draft of the Metrics (accessible at: http://www.organic-center.org/reportfiles/WGA_Comments_March_Draft.pdf).

Our comments focused on water testing requirements and protocols, the provisions governing compost and other soil amendments, and the need for targeting new safety precautions where the risk is greatest. Some of the Center's comments were adopted in subsequent versions of the Metrics and are incorporated in the May 24th version. Other suggestions were adopted in the April draft, but then dropped in the May 24th version.

Significant Flaws

The water testing provisions, collectively, are the most serious flaw in the Metrics. The water testing provisions rely exclusively on testing for generic *E. coli*. While the presence of generic *E. coli* is an indicator of possible *E. coli* O157 contamination, the correlation is not strong, nor sufficiently reliable to judge a water source as safe if it meets the proposed generic *E. coli* standards.

Not only is the basic standard governing water quality based on the wrong organism, the standard applicable to generic *E. coli* is also unscientific and indefensible. Water can be used for irrigation of leafy greens if it contains less than 126 MPN of generic *E. coli* per 100 milliliters of water ("MPN" stands for "Most Probable Number," a measure of the number of microbes in a sample).

The 126 MPN standard is based on an outmoded recreational water quality risk assessment carried out by EPA in the mid-1980s. The EPA estimated the human health consequences from swimming ("full body contact") in water containing various levels of generic *E. coli*. They estimated that eight out of 1,000 people swimming in water containing 126 generic *E. coli*/ml would contract a case of gastrointestinal illness (cases caused by generic *E. coli* would be far milder, on average, than illnesses triggered by *E. coli* O157).

Clearly, new science and more thought needs to be devoted to how to set the standard for both generic *E. coli* and pathogenic *E. coli* in irrigation water. In the interim, the Metrics should be revised to require the testing of irrigation water for *E. coli* O157. Water with detectable levels of *E. coli* O157 should not be used to irrigate fresh cut leafy greens. Period.

This irrigation and cattle watering pond is about one mile north of the outbreak field on the Paicines Ranch. Careful testing of water for pathogens is essential if water from ponds like this are used to irrigate leafy greens.

Only the highest-quality compost should be used in the production of fresh cut leafy greens. The compost should be both stable and tested to confirm the absence of pathogens.

The section of the GAP Metrics addressing composted soil amendments begins with an essential requirement –

> ***"Do not use or apply soil amendments that contain un-composted, incompletely composted or non-thermally treated (e.g., heated) animal manure to [leafy green fields]."***

This commonsense provision will not be easy to apply in practice because the Metrics do not define "fully composted," or "incompletely composted" – two key terms that appear in multiple places in the document.

Appropriately and as recommended by The Center, the Metrics set strict standards for two key pathogenic organisms – Salmonella, and *E. coli* O157.

But the provisions setting forth how compost must be made are inadequate and do not reflect contemporary science. Moreover, the provisions directly contradict the important requirement highlighted above – that unfinished, or "incompletely composted" manure not be applied to production fields.

For compost made in windrows (the most common method), the May 24th version of the GAP Metrics require that the material must be held for 15 days at a minimum of 131 degrees, with a minimum of five turnings, followed by a curing/aging period of "…at least 45 days," for a total minimum composting time period of 60 days. Earlier drafts had required a minimum of just 36 days.

Most experts believe that it takes 90 to 120 days to produce high quality, pathogen-free finished compost. Moreover, experts recommend that the degree of finish in compost be verified through the use of one of several available tests of the stability and biological activity within piles. Some options to do so are explained in the box "Compost Maturity and Stability."

Given the vulnerability of fresh cut leafy greens to pathogenic bacteria, only the highest quality, fully stable, and pathogen-free compost should be used in leafy green production systems. Clearly, a 60-day composting period does not assure that these basic conditions are met. The GAP Metrics should be revised to require at least 90 days in the composting process, along with more sensitive testing protocols to assure that a batch of compost is both pathogen free and stable.

Compost Maturity and Stability

Compost quality standards need to be determined relative to compost end uses. Recently established regulations in Austria establish 13 end-use quality grades for compost, each linked to specific *E. coli* O157 levels.

An index of compost completion should be developed and used to objectively define and measure compost maturity and stability. The key indicators of finished, stable compost are the absence of any ongoing microbial degradation and respiration, coupled with the exhaustion of substrates that are readily available and capable for supporting further growth of pathogens. Multiple studies have shown that *E. coli* O157 thrives under warm, aerobic conditions when available carbohydrates (substrates) are present.

Most experts suggest use of two or more indicators of completion. An index of humification can be used, or measures of compost stability, such as degree of respiration or ongoing emissions of CO2.

In 2001, a compost "Maturity Index" was described in a report issued by the California Compost Quality Council. The report was completed with funding from the California Integrated Waste Management Board. The index draws upon a number of proven, practical lab-based measures of compost quality, and serves as a sound basis from which to develop a protocol to test and verify compost maturity.

A Strategy to Prevent Foodborne Illness Outbreaks

Prevention of foodborne illness outbreaks requires innovation, attention to detail, and diligence from the farmer's field, through the packing plant and distribution system, at retail, and in the consumer's refrigerator and kitchen, or, in the interest of brevity, from "farm to fork."

Pathogens can find their way into food in many different ways, well-known risk factors can be triggered or impacted by many different circumstances. Four strategies must be pursued systematically in the months and years ahead to find and plug holes in the food safety system. These four pillars of food safety are:

- **Monitor, Study, and Probe for Answers**
- **Strengthen the GAP Metrics and Grower-Processor Plans**
- **Farm to Fork Continuity and Diligence**
- **Identify and Deal with High Risk Areas and Circumstances**

Monitor, Study and Probe for Answers

Improving the accuracy, reliability, scope, and frequency of *E. coli* O157 and Salmonella testing all along the food chain is absolutely essential if significant and sustained progress is going to be made in dramatically reducing the frequency of O157 outbreaks.

Given the technical challenges and costs inherent in such testing, the state and federal governments can, and likely will need to play an active role in setting up and financing investments in improved testing capability and infrastructure. In addition, for at least a few years, the government needs to commit funds to lower the costs per sample for individual farmers and processors, especially smaller operations.

To accelerate progress in ongoing research and epidemiological assessments, public support for testing should be coupled with agreement from all parties to –

- Collectively work toward high quality, consistent test methods done by accredited labs in adherence to clear and specific protocols.
- Place test results in a public database so that researchers, inspectors, processors, and buyers can tract progress in reducing the frequency and levels of *E. coli* O157, Salmonella, and other pathogens, and pursue additional preventive measures when hot spots are identified.

One of the most pressing challenges is to review and improve the test methods that will be used to certify that irrigation water sources, soil amendments, and other production inputs meet safety standards set forth in the GAP Metrics. Currently, there is too much variability in the accuracy and sensitivity of these test methods, and as a result, too much room for false positives and false negatives.

The industry-wide costs associated with just a handful of errors in testing methods, whether false positives or negatives, will likely exceed the added costs of adopting the most accurate, sensitive and reliable methods available.

Rapidly enhancing both the scope and frequency, and accuracy of testing for pathogens in water, soil, inputs, and raw and finished product is going to raise enormous technical, practical, and financial hurdles. This is why support from government will be necessary if rapid and consistent progress is

to be made across the whole industry, equally benefiting major corporations and back yard gardeners selling at farmers markets.

Strenghten GAP Metrics and Grower - Processor Plans

The current GAP Metrics acknowledge that new information and technology will emerge that will lead to reconsideration of certain practices, standards, and processes. Initially, the Metrics need to be both stricter and more comprehensive than the Metrics that will be required once better information is obtained on the epidemiology of key foodborne pathogens.

In Section III, a set of additions and modifications to the GAP Metrics are suggested. Other organizations and experts have also submitted suggested refinements to the Western Growers Association. WGA needs to keep this process open and dynamic, and should plan for substantive revisions in the Metrics on at least an annual basis.

It is clear that some growers and processors are going to include added or different preventive measures in their food safety programs; the firewall testing program at NSF is an example. Some diversity in the strategies employed in 2007 to achieve food safety is inevitable and desirable, and should accelerate progress in understanding the best ways to expand margins of safety.

Photo credit: Earthbound Farm

The testing of raw product for pathogens before entering the processing stream can help prevent future outbreaks.

The WGA and other industry groups, in partnership with government funded research teams, should monitor the effectiveness of the novel measures incorporated in individual grower or company food safety plans, with the goal of identifying those that contribute most cost-effectively to added safety. Practices that emerge as reliable and cost-effective can be integrated into future updates of the GAP Metrics.

Raw product testing programs, in particular, open up valuable opportunities for field-level research. Each positive lot identified with one or more pathogen should trigger an immediate assessment of pathogen levels in the field and how they got there. Such real-time field investigations should also assess practices that might have undermined usually effective systems.

Farm to Fork

For safe food to remain so, the intense focus on farm-level food safety in recent months must be matched by equal rigor, innovation, and discipline at all other stages of the food production-processing-distribution-consumption chain. The epidemiology of recent illness outbreaks linked to produce suggests that more attention needs to be directed to the tail end of the distribution chain – e.g., how produce is trucked and managed at regional distribution centers, handled at retail, and whether consumers are keeping product chilled and consuming it prior to the "best used by" date.

One needed change is simple and won't cost much. Processors need to place on the front of their bags or clamshells a clear-cut message to consumers that states:

> ***Do your part in assuring food safety – Keep this product refrigerated and respect the "best used by" date.***

Most fresh cut leafy green products sold in bags or clamshells have shelf lives of 15 to 17 days once product leaves the processing plants, up from five to 10 days just a few years ago when the fresh cut industry took off.

Measured from harvest, product remains fresh and safe under most circumstances for about 20 days. Fresh greens are highly perishable, and prior to the emergence of the fresh cut industry, most fresh leafy greens were consumed within a few days of harvest.

Shelf lives between two and three weeks for leafy greens are clearly pushing the food safety envelope. Success depends, first and foremost, upon continuous, proper chilling. Even a gap of a few hours in proper temperature control can give bacteria an opening that sets off rapid proliferation. The longer the shelf life, the longer the distances covered in distribution systems, especially in the heat of summer, the greater the risk. The more times product must be moved from a building to a truck and back into a building, the greater the risk of problems.

While retailers have continuously encouraged the fresh cut industry to improve product hygiene and extend "best used by" dates, it is possible that the distribution system has become stretched to the point where occasional lapses in temperature control are inevitable.

For this reason, the timing and geographic patterns of recent produce-triggered outbreaks need to be carefully analyzed to see what products caused the outbreaks, how far the products had traveled, whether there were possible gaps in temperature control, and the frequency of illnesses per unit or produce purchased in a given region.

Harvest operations are another key focus of food safety.

For example, in the 2006 spinach outbreak, three states appear to account for a disproportional share of the cases - Wisconsin with 50 cases (almost one-in-four), Ohio with 29, and Utah with 19. California had only 2. Dole surely has records of what percent of the units shipped during Shift A on August 15th went to each state. With this data, it will be easy to calculate illnesses per unit sold by state, by time and distance traveled, and by regional distribution center.

Data may even be available to calculate illnesses per unit sold by a given retailer. This information might prove decisive in identifying a possible breakdown in temperature control at a super market chain's regional distribution center, or in transit to stores, or once product arrives in stores.

If correlations emerge between these sorts of measures of frequency of illnesses with other variables like distance traveled or regional distribution center, these insights would suggest that a breakdown may have occurred somewhere along the distribution system. Such insights will be key in preventing reoccurrences, and this practical reality holds true from farm to fork.

Identify and Deal with High-Risk Areas and Circumstances

Some fields and areas are more vulnerable to *E. coli* O157 contamination than others. As soon as possible, it will be helpful to develop a method to assess the degree of risk of foodborne pathogen problems associated with individual fields. Similar tests and methods should also be developed and applied to production inputs and agronomic practices.

While it will take time and resources to conduct such relative risk assessments, the insights gained will markedly improve the cost-effectiveness of all efforts designed to widen food safety margins.

Almost certainly, in and around the Salinas Valley there are high-risk fields and areas, and those with no history of problems and no known risk factors. Selecting fields in the lower-risk areas and passing up fields with known risk factors is a logical and low-cost option for the industry as a whole. For reasons discussed in Section II, risk adverse companies in 2007 would likely pass up the chance to grow fresh cut spinach on the Paicines Ranch field that the FDA believes was the source of the 2006 outbreak, because of the field's proximity to so many grazing cattle.

Part of a long-run solution for fruit and vegetable producers is devising effective, low-cost interventions to address high-risk crops, fields, practices, and circumstances. Such interventions could include not producing fresh cut produce on certain fields along rivers and streams that are subject to periodic flooding, or when the surface water source used for irrigation has flowed through a beef cattle or dairy farm. Until more is known, it is prudent to err on the side of caution.

The Bovine Connection

Published research has clearly established the risk factors triggering the shedding of *E. coli* O157 on beef and dairy farms. Only some cattle, during certain times of the year, are at high-risk for O157 infections and shedding. These animals can be identified. For the most part, high-risk time periods correlate with heat or other sources of animal stress. Feed-related and animal husbandry risk factors for bovine O157 infections are also known. There are simple, low-cost interventions available to beef and dairy farmers that can moderately to dramatically reduce shedding rates.

Fortunately, wild and farm animals and crop farming have co-existed, side-by-side, for centuries, delivering enormous benefits to the soil, environment, and all animals, including humans.

Photo credit: K. L. Benbrook

Cows under stress and in poor condition are more likely to shed *E. coli* O157. This cow was moving to a new pasture in January 2007 less than one mile from the outbreak field on the Paicines Ranch.

Despite occasional outbreaks of foodborne illness linked to animals, the integration of crop farming and livestock production has been, and will remain an absolutely essential part of American agriculture. The interface between wild and farm animals and crop farming needs to be managed to promote safety, but total separation is neither feasible nor desirable.

References

Aruscavage, D., Lee, K., Miller, S., and LeJeune, J. T. Interactions affecting the proliferation and control of human pathogens on edible plants. Journal of Food Science 71, 89-99. 2006

Dingman, D. W. Growth of *Escherichia coli* O157:H7 in bruised apple (Malus domestica) tissue as influenced by cultivar, date of harvest, and source 3. Appl.Environ.Microbiol. 66(3), 1077-1083. 2000

Rangel, J. M., Sparling, P. H., Crowe, C., Griffin, P. M., and Swerdlow, D. L. Epidemiology of *Escherichia coli* O157:H7 outbreaks, United States, 1982-2002. Emerg.Infect.Dis. 11(4), 603-609. 2005

Solomon, E. B., Potenski, C. J., and Matthews, K. R. Effect of irrigation method on transmission to and persistence of *Escherichia coli* O157:H7 on lettuce. J.Food Prot. 65(4), 673-676. 2002a

Solomon, E. B., Yaron, S., and Matthews, K. R. Transmission of *Escherichia coli* O157:H7 from contaminated manure and irrigation water to lettuce plant tissue and its subsequent internalization. Appl.Environ.Microbiol. 68(1), 397-400. 2002b

Suslow, T. V., Oria, M. P., Beuchat, L. R., Garrett, E. H., Parish, M. E., Harris, L. J., Farber, J. N., and Busta, F. F. Production practices as risk factors in microbial food safety of fresh and fresh-cut produce. Comprehensive Reviews in Food Science and Food Safety 2 (Supplement), 38-66. 2003

Warriner, K., Ibrahim, F., Dickinson, M., Wright, C., and Waites, W. M. Interaction of *Escherichia coli* with growing salad spinach plants. J.Food Prot. 66(10), 1790-1797. 2003a

Warriner, K., Ibrahim, F., Dickinson, M., Wright, C., and Waites, W. M. Internalization of human pathogens within growing salad vegetables. Biotechnol.Genet.Eng Rev. 20, 117-134. 2003b
.

Warriner, K., Spaniolas, S., Dickinson, M., Wright, C., and Waites, W. M. Internalization of bioluminescent *Escherichia coli* and Salmonella Montevideo in growing bean sprouts. J.Appl. Microbiol. 95(4), 719-727. 2003c