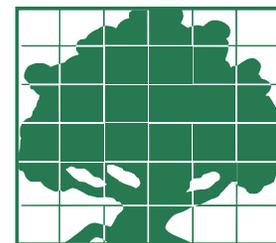


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E. coli in Spinach, Foodborne Illnesses, and Expectations about Food Safety

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The FDA and the produce industry have recognized the potential for E. coli contamination of leafy greens for some time and numerous safeguards were already in place at the time of the recent E. coli outbreak. The failure to prevent or detect the E. coli before the contaminated spinach entered the market amplifies the demand for improved quality assurance in the food supply in general, and produce in particular. There are over 40 billion servings of salad consumed in the United States each year, of which almost three billion are fresh spinach, illustrating the enormity and the importance of the task.

The Center for Disease Control estimates that every year 76 million people in the United States become sick from foodborne illness, 325,000 are hospitalized, and 5,000 die. They further estimate that over 12 percent of these illnesses are linked to produce (i.e., fresh fruits and vegetables). This means that in any given year, we should expect 39,000 hospitalizations and about 60 related deaths due to foodborne illness related to produce. If these illnesses are spread out evenly throughout the year, the expectation becomes 750 hospitalizations and slightly over one death per week attributable to produce consumption. It follows that the 2004 illnesses, including 102 hospitalizations and three deaths, traced to bagged spinach over a three-week period starting September 13, 2006, although tragic, were not out of the norm in terms of numbers. In fact, between 1995 and 2005, 19 individual outbreaks of E. coli foodborne illness were attributed to fresh-cut lettuce and one outbreak in 2003 attributed to fresh-cut spinach resulted in two deaths. Therefore, the recent outbreak of E. coli associated with bagged spinach from California arguably may be more an indication of the efficiency and concentration in the produce distribution system, sophisticated traceability mechanisms in place, and effective government communication rather than an unprecedented spike in the risk level of foodborne illness.

Regrettably, investigators never identify the source for the vast majority of incidences of foodborne illness. What is most notably different about the recent outbreak related to fresh-cut spinach is that there are now 13 confirmed samples of bagged Dole Baby Spinach containing the outbreak strain of E. coli. Precisely because the spinach was bagged and all bagged products contain lot codes on the packaging, the Food and Drug Administration (FDA) could quickly trace these samples back to one shift at the Natural Selection Foods packing facility in San Juan Bautista, California and, eventually, four spinach fields in the Salinas Valley. The outbreak drew national attention due to the geographic dispersion of the reported illnesses spanning 26 states. But although the FDA eventually narrowed the location of the investigation, it has been unable to identify the mechanism of contamination or rule out additional cross contamination. Therefore, neither the industry nor the FDA can assure consumers that the problem is solved or that similar problems will not arise in the future. For many consumers, the advisory to avoid bagged spinach has evolved into apprehension about all spinach, all bagged salads, and any type of salad even though no E. coli was found on lettuce and none of the contaminated spinach was grown outside of the Salinas Valley. The Mexican government's temporary refusal of lettuce shipments from the United States and

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Table 1. U.S. Per Capita and Total Consumption of Lettuce and Fresh Spinach, 2004

	Fresh Spinach	Leaf Lettuce	Head Lettuce	Total
Per capita consumption (pounds)	1.8	11.2	20.9	33.9
Per capita servings per year	10	59	111	180
Number of servings (billion)	3	17	33	53

Canada’s refusal to accept any U.S. spinach further fueled fears.

Economic Impacts

The long-term economic impact on agriculture is still uncertain and depends almost entirely upon consumer response in terms of changes in patterns of leafy-green consumption and the duration of those changes. Fresh spinach sales totaled \$157 million in 2005 and accounted for only seven percent of the \$2.1 billion in sales of leafy greens. Almost half of leafy-green sales were head lettuce, one-fourth leaf lettuce, and one-fifth romaine (Figure 1). Looking at harvested acreage, California represents about three-fourths of all lettuce and fresh spinach acreage in the United States (Figure 2). This means that a disruption in the sale of spinach

capita consumption of leafy greens increased from about 26 pounds per person a year to 34 pounds (Table 1). Fresh-spinach consumption is only a fraction of this but showed rapid growth from 0.6 pounds per person in 1994 to 1.8 pounds in 2004. This rate of consumption translates into 180 servings of salad per person a year; roughly a salad every other day. It also means that there are over 50 billion servings of salad consumed in the United States each year, of which almost three billion are fresh spinach. About 80 percent of households purchase salad, with consumption tending to be slightly lower for families earning less than \$20,000 per year (Figure 3). Consumers of all ages purchase spinach, with only a slight decline noticed in consumers over 59 years of age (Figure 4).

According to the International Fresh-Cut Produce Association, fresh-cut produce sales totaled \$15 billion in 2005 through all market channels and \$6 billion at retail alone, accounting for about 16 percent of all supermarket produce sales. Packaged salads are slightly over half of all fresh-cut supermarket sales, totaling over \$3 billion in 2005. About half of all produce enters the food supply through food service (restaurants, hospitals, military, and cafeterias) but no data are available for sales by category.

Efforts to Reduce Risk

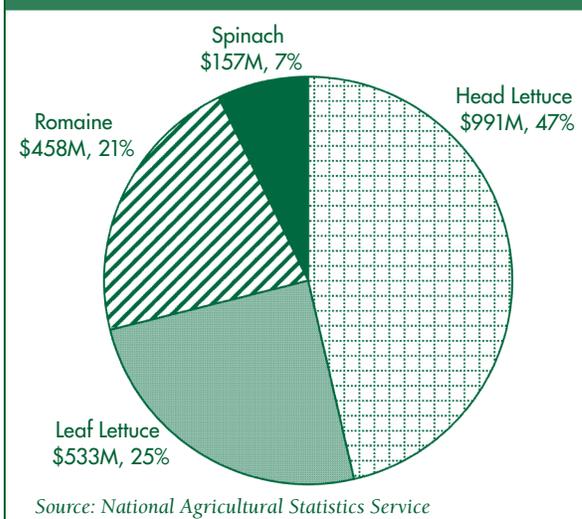
The FDA and industry have recognized the potential for E. coli contamination of leafy greens for some time. In 1998 the FDA issued the “Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables,” including Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs), now recognized as industry standards. In February 2004, the FDA wrote a letter to the lettuce and tomato industries airing concerns regarding continuing outbreaks of foodborne illness. Later that year, the FDA posted its “2004 Produce Safety Action Plan” and in late 2005, issued a letter to California firms that grow, pack, process, or ship fresh and fresh-cut lettuce.

The FDA further developed the Lettuce Safety Initiative to support the goals of the action plan and to coordinate with the California Department of Health Services and Department of Food and Agriculture in recognition that a majority of outbreaks of E. coli related to lettuce were traced back to production in California. The initiative’s objectives are summarized as follows:

- 1) Assess current industry approaches and actions to improve lettuce safety;
- 2) Alert consumers early and respond rapidly in the event of an outbreak;
- 3) Identify practices that lead to contamination and then develop or refine guidelines and policy that will minimize future outbreaks, and
- 4) Consider regulatory action.

The Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture began a voluntary program called Qualified Through Verification (QTV) for the fresh-cut produce industry in 1996. The user-fee program works with individual companies to develop a hazard-analysis plan tailored to their production facility and verifies effectiveness though unannounced on-site audits. Among other safeguards,

Figure 1. 2005 Farmgate Value of Leafy Greens: \$2.1 Billion



the AMS expects firms to test for E. coli as assurance of good sanitation practices. The program promotes proactive prevention of contamination during production, as opposed to detection after the fact. The QTV validation program provides firms with a means of quality assurance for their customers.

Jumping to Conclusions

During the recent E. coli outbreak, early suspicions focused on organic agriculture because of the common practice of using composted manure as fertilizer. However, federal law requires manure used as fertilizer in organic production to be fully composted, which would kill any E. coli present. Further, conventional vegetable growers typically also use composted manure on their fields to improve water infiltration. At the same time, grower groups blamed packers and processors blamed growers. Public criticism also turned to concentration in vegetable production and distribution. At the time of the outbreak, the packing facility linked to the outbreak, owned by Natural Selection Foods, packed for over 30 labels and provided spinach to five other companies. Those companies also issued recalls. Natural Selection Foods farms 24,000 acres of its own and also buys from numerous other growers. Under its Earthbound label, Natural Section salads are available in three-fourths of all grocery stores in the United States.

Two companies, Dole and Fresh Express, account for 88 percent of the packaged salad sold in the United States. This level of market penetration provides a situation where contaminated product can cross the nation in a short period of time. But it also creates a situation where large grower/shippers have the money and motivation to invest in food safety programs. However, the quality assurance from a grower/shipper is only as high as that of its poorest grower.

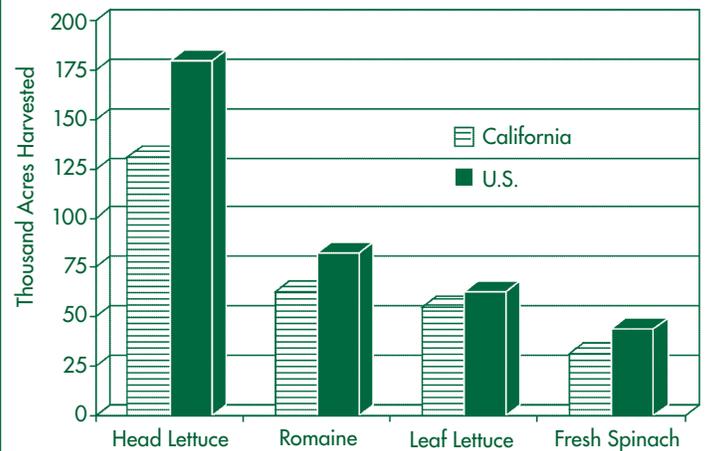
Quality Assurance

The recent E. coli outbreak amplifies the demand for improved quality assurance in the food supply in general, and produce in particular. Increased assurance inevitably means increased spending. The obvious question becomes whether it is most cost-effective to improve prevention of contamination or improve detection, given a finite quality assurance budget. Natural Selection and other major facilities already:

- (1) Maintain sanitation programs following Good Manufacturing Practices developed by the FDA;
- (2) Employ a quality assurance supervisor to continuously monitor chlorine levels of rinse water and the temperature of the plant;
- (3) Hire an independent lab to test for bacteria as part of their quality assurance programs, and
- (4) Participate in the QTV Program.

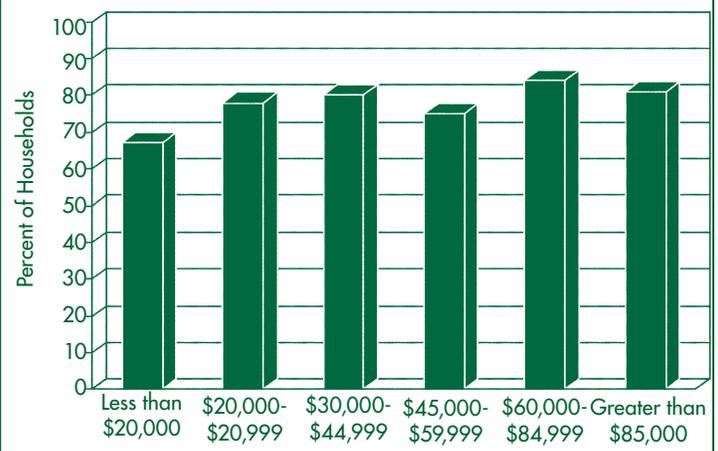
Natural Selection has issued a statement that they will

Figure 2. 2005 Production of Leafy Greens in the United States and California



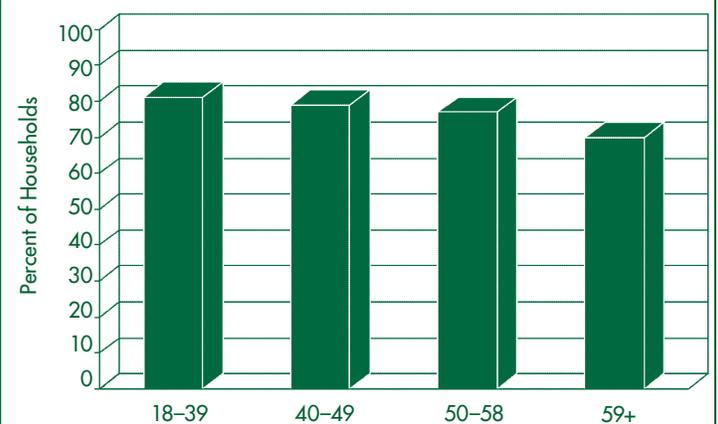
Source: NASS

Figure 3. Percent of Households Purchasing Salad by Income, 2005



Source: Produce Marketing Association

Figure 4. Percent of Population Purchasing Salad by Age, 2005



Source: Produce Marketing Association

“now be testing all of the freshly harvested greens before they enter our production stream.” They will also be working directly with growers “from seed to harvest, inspecting seed, irrigation water, soil, soil amendments, plant tissues, and wildlife—all of which will be tested, monitored, and certified.” These added inspections may prove to be impractical both from a cost and time perspective.

The current and proposed assurances raise further questions. Buyers, such as supermarket chains, set standards for food safety and they require that their suppliers meet these standards. In turn, because there is so much at stake, large grower/shippers and packers are highly motivated to work with individual growers to minimize risks to meet buyers’ standards. Third-party private firms offer certification of compliance with Good Agricultural Practices and Good Manufacturing Practices, but the standards for certification are not regulated by the government. There is no government accreditation process for third-party inspectors. Thus far, industry has worked closely with government to develop GAPs and GMPs. The most critical question to answer in the current situation is whether or not problems arose due to a failure to follow known safe practices or if the current situation has brought to light a previously unidentified source of risk. Both scenarios point to the need for additional research to establish new or revised protocols that further reduce the risk of foodborne illness. The current situation also points to the need for an excellent crisis-management plan as part of any quality assurance program. At the same time, while American consumers have every right to demand and expect the highest standards in food quality, they must also accept the fact that zero risk is not a physically attainable goal.

Increased Food Safety Standards

Soon after the FDA lifted the spinach advisory, the Western Growers Association called for food safety regulations for produce. In early November the California Farm Bureau Federation, the largest farm organization in California, followed by announcing it is working with Western Growers



Fresh spinach sales totaled \$157 million in 2005 and accounted for seven percent of the \$2.1 billion in sales of leafy greens.

Photo: UC Regents

and other organizations “to develop self-imposed mandatory food safety regulations.” The statement went on to suggest the possibility of creating a marketing order or marketing agreement to fund the development of mandatory safety standards at all stages of production from farm to table.

In fact, a marketing board already exists for California lettuce. The California Lettuce Research Board, formed in 1973, operates under the authority of CDFR and is financed through assessments on each carton of iceberg and leaf lettuce harvested in California.

In recent years, the board has awarded over half of available funds to breeding for disease resistance. The remaining funds have been for nutrient and cultural research. Future funds could be directed toward the creation of food safety standards.

The FDA publication, “Guidelines to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,” would undoubtedly serve as a starting

point. Although they address all known sources of contamination, by design, these voluntary guidelines were not written in regulatory language.

California and federal officials have now found evidence that nearby cattle and wild boar are the probable sources of the recent E. coli contamination. The guidelines include the presence of wildlife and livestock as potential sources of microbial contamination and recommend “to the extent possible, where high concentrations of wildlife are a concern, growers should consider establishing good agricultural practices to deter or redirect wildlife to areas with crops that are not destined for the fresh produce market.” Terms like “to the extent possible” are impossible to enforce.

Regulation and enforcement are limited by current scientific knowledge. The FDA guide “focuses on risk reduction not risk elimination.” It goes on to say that “current technologies cannot eliminate all potential food safety hazards associated with fresh produce that will be eaten raw.” Nonetheless, the European Union and New Zealand are beginning to move toward the adoption of mandatory food safety regulations for fresh produce and away from voluntary guidelines. These actions could put additional pressure on the U.S. industry to implement changes.

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