

THE HISTORY, POLITICS & PERILS OF THE CURRENT FOOD SAFETY CONTROVERSY



CAFF Guide to Proposed Food Safety Regulations

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Executive Summary

After contaminated bagged spinach sickened several hundred people in 2006, protection of food from human pathogens became an even higher priority for farmers across the U.S. It had become clear that *E. coli* O157:H7 and other related pathogens were highly virulent and apparently present across many farm environments. Farmers, ranchers, consumers and public advocates are now engaged in a debate over the direction of new regulations and initiatives intended to address food safety. This document provides background to those interested in a deeper understanding of the food safety debate.

There are several problematic issues to be addressed. One of those is the need to reconcile food safety regulations with environmental stewardship. Common to most of the official food safety efforts is a call for vigilance in keeping wildlife, cattle and manure away from crops. While there is some evidence that wild pigs and other wildlife harbor human pathogens, there is little evidence on persistence in wildlife or that they are source reservoirs of O157:H7. The on-farm impact of the new rules has been removal of wildlife habitat, fencing of farm fields, and poisoning of rodents and other animals. Critical practices to protect water quality and increase biodiversity are being discouraged. Water quality specialists, farmers, and consumers are distraught at the resulting environmental disruptions.

Another issue to be considered is the presence of reservoirs of *E. coli* O157:H7 in large dairies, cattle feedlots, and in the general farm environment. The beef industry has its own problems with O157:H7 as a contaminant of meat and the number of outbreaks was particularly high in 2007, despite 14 years of costly regulation. Reducing the reservoirs and movement of the pathogen would benefit both the produce and the beef industries, but current regulatory initiatives provide no incentives for such partnerships and tend to use a narrow farm-by-farm approach.

Finally, the fixed costs associated with some of the new regulations will have a disproportionate impact on growers who specialize in a diversity of crops, or who have limited resources. Most of the regulations have been developed by produce buyers and technical experts who are only familiar with large-scale cropping production systems. Subjecting all producers to the regulations seemingly required for industrial production will limit market entry of smaller farmers who can least afford compliance. In turn, this will limit the choices of consumers by reducing the types of farms and farm practices that they can support.

Food poisoning can be associated with many different foods, but the new regulatory initiatives are directed at fresh vegetables in general, and greens like spinach and lettuce in particular. One of the most successful efforts, the California Leafy Greens Marketing Agreement, focuses on an ill-defined group of crops called "leafy greens," many of which are used in the conveniently packaged "ready to eat" bags of salads, spinaches, lettuces and lettuce hearts that have become so ubiquitous on supermarket shelves.

The practice of bagging cut greens in this "ready to eat" or "ready to serve" form is relatively new, but the industry has been very successful and is growing rapidly. It caters to

the supermarket shelf as well as food service, and it has become known as the “fresh-cut” industry. In fresh-cut processing plants, safeguards are taken to prepare fruits and vegetables to be eaten directly out of the bag. The processors, handlers and growers associated with fresh-cut leafy greens are large-scale, located primarily in California, secondarily in Arizona.

Despite precautions to protect consumers from pathogens, there are a number of risks uniquely associated with the fresh-cut industry: cutting tender young plants, mixing them in large batches potentially from multiple sources, and shipping them in bags that require constant refrigeration to maintain freshness and safety. These issues are very different from any potential risks that might be associated with growing and marketing whole produce in a more traditional, non-processed manner.

The multi-state outbreak of September 2006 was associated with bagged spinach. However, when investigators first became aware of the problem, even after narrowing it down to spinach, it took them several critical days before they pinpointed it to bags from a specific processing plant, manufactured on a specific day. Initial FDA warnings advised people not to eat any fresh spinach until further notice, shutting down nearly the entire spinach market in the U.S.

The approaches for protecting produce from pathogens that are under consideration (or in place) can be summarized as follows:

- The use of crop-by-crop Marketing Act programs that give a small number of handlers or growers the responsibility of enforcing a set of on-farm food safety standards. In this scenario, industry leaders exercise significant control.
- Regulations enforced by a centralized state or federal bureaucracy (for example, the Food and Drug Administration). In this scenario, significant authority is ultimately in the hands of elected politicians.

Federal and State Marketing Acts have generally been used to address marketing and trade issues. Their use in food safety is a new development. The California and Arizona Agreements (for example the California Leafy Greens Marketing Agreement) are potentially the first steps before a national law is adopted. This report outlines the following reasons why (mandatory) Marketing Act Orders and (voluntary) Agreements are not well suited for regulating on-farm produce safety:

1. Marketing Act programs give control to a small group of the largest processors or growers.
2. Marketing Act programs can give processors and handlers control over on-farm production practices, which can result in rules that are impractical and ineffective.
3. Marketing Act programs and other leafy greens food safety approaches have not distinguished between fresh-cut and whole produce.
4. The crop-by-crop nature of the Marketing Acts doesn't work well for farms growing more than one crop.
5. Marketing Act programs and other approaches currently in vogue put farmers in conflict with environmental stewardship.

6. Marketing Act Agreements require growers to follow regulations for which the enforcement agencies take no responsibility and accept no liability.
7. Marketing Act programs and other current approaches do not address important issues beyond the farmers' control.
8. Using Marketing Acts for food safety is beyond the original purview of the Marketing Acts and is probably illegal.
9. Over the long term, using the Marketing Acts for farm food safety will diminish consumer choice as well as farmers' freedom.
10. Using the Marketing Acts for farm food-safety can lead to massive regulation without substantially improving food safety.
11. Using Marketing Act programs for food safety exercises national or state control over an inherently local industry, primarily benefiting the largest agricultural entities.

This report concludes with eight recommendations that should be included in a better approach to farm food safety:

1. Reduce human pathogens throughout the pathogen cycle in the farm environment. On-the-farm and in-the-processing plant efforts will have limited success on their own. It is critical to add a food safety component that addresses the general environment and prevents contamination of farms and water.
2. Develop and enforce specific food safety regulations for all phases of the fresh-cut industry, including processing plants. Food safety for the farmers who do not choose to grow for fresh-cut is a separate issue, with its own requirements depending on risk, farm size, and history.
3. Encourage environmental stewardship as an integral part of food safety. Good Agricultural Practices on the farm have to mesh with Best Management Practices of the Endangered Species Act, Clean Water Act and Air Quality regulations.
4. Provide educational materials on food safety to limited-resource growers and provide all farmers with the tools they need to address food safety on their farms.
5. Identify and track serious human pathogens in watersheds. Several of the largest outbreaks in North America were caused by contaminated water, suggesting that water quality and public health agencies need to take a greater role in addressing the threat.
6. Support partnerships between ranchers and dairymen, researchers, watershed or water quality experts, and cooperative extension specialists to address food safety issues.
7. Conduct research into reducing the human disease impact of O157:H7.
8. Conduct research into food safety that is practical for farms, ranches and dairies. Practically oriented studies should be conducted into: understanding the cycling of the pathogen through soils and rangelands; understanding the relationships between human enteric pathogens contaminating food and the use of antibiotics in animal production; protecting the microbial safety of all farm inputs; and animal husbandry practices that reduce the incidence and shedding of O157:H7.

I. A New Industry

A new processing industry grew up over the last twenty years, delivering minimally processed produce in retail packages such as plastic bags or clamshells for consumers, and larger bulk plastic packages for wholesale food service use. Most people recognize the ready-to-eat retail bags of baby carrots and leafy green salads, which can include spinach, lettuce and spring mixes, or hearts of lettuce.

Now called “fresh-cut,” this industry caters to both retail and food service. Fresh-cut for food service is similar to retail except the quantities are typically larger, such as 10- to 40- pound bags of shredded lettuce; or more specialized, such as sliced tomatoes sold in disposable packaging that can be slotted directly into a refrigerated food preparation table.

Major buyers of fresh-cut food service packs include fast food chains, restaurants, and institutional food services including: airlines, hospitals, universities, prisons, the military, and others. Fast food chains are the largest buyers of some U.S. fruits and vegetables. For example, Subway is the largest buyer of tomatoes and McDonald’s is the largest buyer of apples. If retail bags or packages are called ready-to-eat, food service bags or packages could be called ready-to-serve.



Boosters of the fresh-cut industry downplay the processed nature of the product, but what puts the “processing” in fresh-cut produce are the steps taken to prepare fruits and vegetables for direct use and to ensure a marketable shelf life. These include: worker and plant sanitation, washing, sorting, cutting, peeling, shredding, grinding, chlorinated rinses, control of hydration while cooling, modified atmosphere or vacuum packing, and sophisticated film technology for packaging.

“Fresh-cut” is an unusual food processing industry. What puts the “fresh” in fresh-cut is the atypical processing goal of delivering still-living plant tissue in a ready-to-eat, appealing form to consumers. Normally the goal of food processing is microbial safety and long-term stability. Traditional methods include salting, drying, pickling, preserving, and fermentations. Industrial methods include pasteurization, irradiation, aseptic packaging, vacuum dehydration, canning and freezing.

Freezing, canning and ultra-pasteurization with aseptic packaging leads to stable food products with years-long “best-used-by” shelf lives. Conventional food processing includes a “kill step” which controls pathogenic organisms and other biological contaminants. It also stops all biological activity of the food.

Despite precautions to protect consumers, cutting, peeling, grinding, or other steps that take whole vegetables and process them into ready-to-eat form also remove natural barriers to pathogens, like peels or intact surfaces. They expose cut surfaces and induce wound responses, both of which can increase microbial attachment or growth, depending on the vegetable and pathogen involved. Some research shows that *E. coli* cells favor the cut edges and bruised areas of lettuce leaves.¹

Processing fresh-cut vegetables in large batches from multiple sources also increases the statistical chance of a microbial pathogen presence on one or more of the fruits or vegetables in a batch. When contamination is present, it has the opportunity to be spread throughout an entire production lot via: contact in mixing and product flow, contaminated processing equipment, or contaminated wash water. A contaminated lot can then be shipped nation-wide.

Whole fresh produce may be easier to effectively wash than fresh-cut. If a single contaminant on a fruit or vegetable is not washed off, the opportunity to cause infection is contained to one location and one or a few people. In contrast, the same single contamination can act as an inoculum in a fresh-cut production lot, which can then expose many consumers at multiple locations. The probability of a multi-state outbreak is higher with fresh-cut produce than for whole produce.

The length of time between cutting and consumption, by itself, allows a greater chance of pathogen growth in the bagged or packaged product. Processing into ready-to-eat form, then, makes “fresh-cut” fruits and vegetables less safe than whole fruits and vegetables. The chlorinated rinses used in packing plants are not considered adequate kill steps for microbial safety. In order to prevent pathogen growth, and also to maintain product quality, refrigeration (a ‘cold chain’) needs to be maintained from harvest through processing, transportation, retail delivery, and home consumption. Any break in the temperature of a fresh-cut product at any step in the marketing chain increases the risk of contamination, unlike conventionally processed products. If cold chains are maintained, effective post-cutting storage times that maintain high quality are 14-18 days for lettuce salads, over 21 days for baby carrots, 4-9 days for pepper and tomato dices.²

Actual cold chains often fall short of the ideal used in research. They can be studied and followed using radio frequency identification or other sensors. Marita Cantwell, a U.C. Davis Cooperative Extension Vegetable Specialist, illustrated the loss of ideal temperature under real-life conditions using private data. Her study showed temperature rising moderately in two separate stages: on leaving processing plant storage for long distance (refrigerated) transportation, and in retail store storage coolers before sale. It showed a higher temperature rise while the product was locally distributed after long distance transportation and a more dramatic rise when bags were displayed on the retail shelf.³

¹ Frank, J., University of Georgia.

² Cantwell and others, 2007.

³ Cantwell, Sept. 2007.

The loss of a cold chain can also be inferred from the geographic pattern of a food borne outbreak. Bill Marler, a leading *E. coli* plaintiff's attorney, spoke to leafy green growers and processors at a meeting in the Steinbeck Center, Salinas, California on February 28, 2007. He noted that the cluster of Wisconsin illnesses, from the September 2006 Dole spinach O157:H7 outbreak, made most sense if there had been a break in the cold chain either in long distance transportation, or in an intermediate storage facility. Unlike other processed fruits or vegetables, fresh-cut food safety is uniquely dependent on what happens before processing begins and after the product leaves the plant.

Grading standards for quality could help address these issues and impose best-used-by dates correlated with biological safety. Unfortunately, "There are no U.S. grade standards for fresh-cut products."⁴ Furthermore, there are only guidance recommendations from the FDA to the fresh-cut industry for safety-based used-by dates.⁵ In practice, individual processors and brands set their own best-used-by dates.

The structure of the industry

The fresh-cut industry has grown rapidly. Most of the time it delivers safe and appealing products to consumers, either directly through retail bags or indirectly through food service packs. The product looks fresh, tastes fresh, and seems fresh. If it is not exactly the same as fresh produce, due to storage time and conditions, it is close enough and highly convenient.

For food service buyers, there are also strong economic incentives to use fresh-cut, including: worker safety (fewer cuts), lower sanitation costs, product uniformity, reduced preparation time, and more efficient use of space for both preparation and storage.

Starting with zero sales in 1985, retail fresh-cut supermarket sales reached \$89 million in 1989 and \$600 million in 1994.⁶ Roberta Cook is the UC Davis Cooperative Extension economist who covers the fresh-cut industry. She analyzes scanner data from Nielsen and Information Research Institute retail sales, but food service has no official sources of data.⁷ Her estimates of fresh-cut product sales are presented in the following table:

Table 1: Fresh-cut Sales: 1994-1995

	1994	1999	2003	2005
Retail				\$6 billion
Food Service				\$9 billion
Total Sales	\$3.3 billion	\$6.0 billion	\$8.9 billion	\$15 billion

Source: Cook, personal communication.

⁴ Kader, 2007.

⁵ Gorny, Sept. 2007; FDA, March 2007.

⁶ Burros, 1995. From Fresh-Cut Produce Association data.

⁷ Cook, personal communication.

Retail dollar values of bagged, fresh-cut produce are approximately: packaged salads 50%, baby carrots 15%, all other vegetables 15%, and all fruits 20%.⁸

Fresh-cut has become a highly concentrated industry. This can be shown for fresh-cut salads, where crops are mainly grown in California, and then processed and sold by a small number of companies. A similar analysis could be done for concentration in baby carrots, fresh-cut apples, and food service tomatoes.

Retail analysis of bagged, fresh-cut salad sales from 2006 data shows market shares as:

Table 2: Market Dominance by Brand

Fresh Express (Chiquita)	41%
Dole	31%
Ready Pac	8%
Earthbound Farms (Natural Selection Foods)	6%

Source: Cook, 2007.

Four companies controlled 86% of the fresh-cut salad market in 2006. In fact, the market may be becoming even more consolidated. Fresh Express, captured approximately 47% of the value-added salad market in 2007, or nearly one half of all sales.⁹

California produces 51% of all fresh vegetables, by value, in the United States.¹⁰ In 2005 this included 74% of head lettuce, 84% of leaf lettuce, 76% of romaine lettuce, and 73% of spinach grown in the U.S. Arizona and California produced 185,000 of the 189,000 acres of head lettuce in 2005, the largest component of the leafy green market.¹¹ The smallest (statistically reported) leafy green crop was spinach on 36,000 acres. California grew



⁸ Rounded from Cook, Sept. 2007.

⁹ Prevor, Oct. 2007.

¹⁰ USDA NASS, California Agricultural Statistics 2006.

¹¹ Zischke, 2006.

73% of the 2004-06 U.S. spinach crop, Arizona grew 12%, and New Jersey grew 3%. These are the top producing states, with 12 others reporting production of at least 100 acres.¹²

California farmers who grow for the lettuce and spinach markets are part of a small group of farmers who operate at a large, or very large scale. The most recent data for California farm size in lettuce production comes from the *2002 Census of Agriculture*. Eighty-three percent of all California lettuce comes from just 102 farms with 500+ production-acres. Just 59 farms grew 69% of the lettuce crop on farms of 1,000 acres or more. Spinach was grown by 232 farms on 28,017 acres in 2002. The *Census* does not report spinach by farm production size, however, only one farm has grown almost all of the spinach for Fresh Express, the largest processor.¹³

Farms that grow major leafy green crops are similar to farms for other processing crops.¹⁴ Leafy green farming appears distributed among a few mega-farms with over 10,000 producing acres, a modest number of mid-sized farms (for California), and a large number of quite small farms with a small percentage of production. Only the largest of these growers participate in the concentrated, national scale, fresh-cut processing industry. In general, 13% of all California vegetable farms grow 90% of the total processing acreage.¹⁵

For fresh-cut leafy greens, this fits the picture of a processing industry that requires large-scale farms, primarily in California and secondarily in Arizona, supplemented primarily by Mexican imports from equally large-scale farms, partnered with or controlled by California and Arizona growers.¹⁶ Food service and concentrated distribution chains require a year-round reliable supply of fresh-cut produce. A few very large, reliable farming operations can grow crops year round on California's Central Coast, Arizona, and northern Mexico which are able to satisfy a significant part of the volume needed at the required quality.

The California Leafy Green Marketing Agreement (LGMA) defines leafy greens as follows: "iceberg lettuce, romaine lettuce, green leaf lettuce, red leaf lettuce, butter lettuce, baby leaf lettuce (i.e. immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard."¹⁷

¹² USDA ERS 2007, using 2007 Census data.

¹³ Schmit, Oct. 2006.

¹⁴ Fresh-cut production is not identified in agricultural statistics. Lettuce and spinach grown for "fresh market" can be used as surrogates for analysis because of their importance in leafy green salads and the scale and dominance of California production for both fresh market and the fresh-cut industry.

¹⁵ USDA, 2004; CDFA, 2007. Analysis by Cohen.

¹⁶ It wasn't always this way. The fresh-cut salad industry was started by small-scale organic growers, but taken over by industry.

¹⁷ CDFA Marketing Branch 2007. "Spring mix" remains an undefined term.

The *Census of Agriculture* is unfortunately not terribly useful for accurately answering questions about actual number of farms growing “leafy greens”. The *Census* is also not useful for separating out “fresh-cut” as produce going for processing. The best that can be done is containing or limiting the farm data to be accurate within severe limitations, as we have attempted here.

Using data from the 2002 *Census*, we can combine California farms in the following categories and be sure to have included all farms growing leafy greens as defined by LGMA: all lettuce, escarole/endive, kale, cabbage; and including “vegetables mixed” and “vegetable other” to cover arugula, chard and “spring mix.” The total number of farms in these categories is 1,810, or less than 2.3% of California farms accounting for all leafy green production, (not just for fresh-cut.)¹⁸ In reality, the number is much lower because many farms grow several of these crops at once (and are thus counted twice in the *Census* crop lists.) We estimate that there are likely no more than 1,400 leafy green farms in California or 1.8% of the total number of farms.

The number of these farms growing for the fresh-cut industry is much less than the number of all leafy-green farms. A lower bound of the number of fresh-cut leafy green farms would be about 100 (twice the number of farms used by the largest processor for 47% of fresh-cut salad sales). This is about 2.6% of all California vegetable growers, or less than 0.1% of all California farms.

The politics of describing fresh-cut



Fresh-cut is a unique marketing and processing industry with unique safety and economic issues not found in whole fresh produce. These issues are impacted by on-farm practices, handling, processing, shipping, and end use. The fresh-cut industry includes risks from “processing” in a plant or in the field, packaging in bags or other containers, and potential magnification of a contamination problem from a single incident.

According to our data, the fresh-cut salad industry is a highly concentrated processing industry, dependent on a small group of large and very large farmers, with unique food safety issues. In contrast, the industry itself attempts to describe the food safety and economic problems of fresh-cut as on-farm issues for all produce growers, without distinction for the differential risks of the marketing chains. While on-farm contamination can travel through either fresh-cut or whole-fresh marketing chains, in reality, disease

¹⁸ This approach assumes no overlap (for example, a farm grows spinach and lettuce). However, on average each farm grows over three vegetable crops.

contamination issues in produce are dominated by handler issues, processing issues, and the fresh-cut market segment.

Processors are the known sources of many multi-state produce pathogen outbreaks and recalls of the last twenty years. Processor/handler contaminations include repeated outbreaks due to *Salmonella* on Roma tomatoes from 1990 to 2004. The first trace-back was in 1993 to the wash tank of a South Carolina packinghouse. Hazard Analysis and Critical Control Point (HACCP) controls at the wash tank stopped further outbreaks at that plant.

“Of seven subsequent tomato-associated *Salmonella* outbreaks, six have been traced to other packinghouses in the southeastern United States. Although produce packinghouses are specifically exempt from the requirements of Good Manufacturing Practices (GMPs), FDA guidance to the produce industry encourages GMP controls for water used in packinghouses. However, the extent to which FDA guidance has been adopted by the industry is unknown... Understanding the mechanism of contamination and amplification of contamination of large volumes of tomatoes is critical to prevent large-scale, tomato-associated outbreaks.”¹⁹

The key point is the role of processors and handlers in *amplification*, whether a disease inoculum comes from the farm environment, handling equipment like cartons, employees, or contaminated wash water, including contaminated wells as sources.

Fresh-cut is responsible for many food-borne outbreaks and recalls of produce in recent years, including: the September 2006 Dole Spinach outbreak and massive spinach recall, which was traced through retail bags; the November/December 2006 Taco John and Taco Bell outbreaks from food service lettuce; and the September 2007 Dole “Hearts Delight” recall of bagged lettuce.

An analysis of FDA records conducted by the Community Alliance with Family Farmers²⁰ found that since 1999, there were 12 outbreaks of *E. coli* O157:H7 traced to California leafy greens, resulting in 539 reported illnesses. Of those 12 outbreaks, 10 (80%) were on fresh-cut leafy greens and those 10 outbreaks involved 531 (98.5%) of the illnesses. The actual numbers may be closer to 100%, but the FDA is unable to definitively categorize some sources and they do not appear to have been maintaining separate records for fresh-cut until 2002.

Fresh-cut processors and handlers contributed to the detected outbreak record. However, handlers and fresh-cut processors are not specifically regulated for fresh-cut food safety. Produce handlers such as packinghouses are exempt from FDA regulation and fresh-cut processors are only covered by general food processor rules.

¹⁹ “Outbreaks of Salmonella...” April 2005.

²⁰ See Table, pg 21 of this document, plus information on the 2006 outbreaks, or the CAFF website, www.caff.org.

The FDA's "Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (March, 2007) states:

"[This document] contains non-binding recommendations...This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public...

"FDA's guidance documents, including this document, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required."

The susceptibility of fresh-cut processing to contamination issues would seem to require specific attention by regulators. Instead, so far, fresh-cut processors have only come under general food safety regulation. In 1997 it was reported that an FDA-regulated plant was inspected by the FDA, on average, only once every 10 years.²¹ In 2006 the overall average reported was 5 years,²² and for leafy green processors every 4 years.²³

As for California agency inspections, an Associated Press review conducted in 2007 "found that since last year's *E. coli* outbreak, California public health inspectors have yet to spot-test for bacteriological contamination at any processing plants handling leafy greens."²⁴ California's Department of Health Services (DHS) was asked if there would be additional inspections of leafy green processors to coordinate with the California Department of Food and Agriculture inspections of farms for the LGMA in the summer of 2007. The response was that "There are no statutory provisions, nor any targeted funding, for special inspection teams dedicated to leafy green processors."²⁵ DHS is supposed to inspect registered food processing facilities every year, but this can be waived.²⁶

Ensuring that every leafy green fresh-cut processing facility and every leafy green handler continuously operates according to the FDA Guidances²⁷ for their facilities, and according to state and federal food safety acts, would seem a reasonable first step. *This seems like a better approach than the proposals that impose governmental regulation upon every farmer in the country who grows a crop that may or may not be used for fresh-cut.*

²¹ US FDA-CFSAN, 1997.

²² Hileman, 2006.

²³ Burke, Washington Post.

²⁴ Burke, AP.

²⁵ Cohen, email records, 2007.

²⁶ California Health and Safety Code 110466(b), 01/01/2007.

²⁷ US FDA, 2007.

II. A New Pathogen: *E. coli* O157:H7

On November 5, 1982 the Centers for Disease Control reported that the Epidemic Intelligence Service had connected four dots. "Since the beginning of August 1982, stool isolates of *Escherichia coli* serotype O157:H7 have been identified at CDC from specimens obtained from four patients in two states. Three of four patients had an unusual bloody diarrheal illness... associated with eating hamburgers at restaurants of one national chain."²⁸

Looking back, 15 years later, Dr. Stephen M. Ostroff of the CDC noted:

"...it is striking to discover how many of the now classic features of *E. coli* O157:H7 infection could be identified in those four initial patients -- these features are typical of hemorrhagic colitis, including abdominal cramping and non-bloody diarrhea rapidly progressing to bloody diarrhea in the absence of prominent fever. However, one element of this disease was not mentioned in the 1982 report. None of the four patients developed hemolytic uremic syndrome (HUS) nor was it mentioned as a potential complicating factor. The combination of the severity of the clinical syndrome, the frequency of severe complications, and the lack of specific therapeutic interventions account for the perception of *E. coli* O157:H7 as one of the most feared emerging pathogens."²⁹

It was so unusual to find a severe disease associated with *E. coli*, a normal part of human microbial ecology, that the CDC's 1997 definition of hemorrhagic colitis associated with O157:H7 included, "Hemorrhagic colitis appears to be a distinct clinical entity, characterized by severe crampy abdominal pain, grossly bloody diarrhea, little or no fever and the absence of usual pathogens in stool."³⁰

Clinical language is neutral, diagnostic, and precise but may not communicate well to non-physicians. Enterohemorrhagic colitis was described to the author by a medical doctor field investigator for the CDC, after the juice outbreaks in 1996 and 1997. She said, "O157:H7 is really horrible. We had to watch young children -- infants -- bleeding the entire lining of their intestines out through their rectums. Mostly the treatment consisted of rehydration and general support."³¹ Hemolytic uremic syndrome (HUS) describes the severest symptoms due to O157:H7, which can lead to kidney failure and death.

Infection and symptoms from O157:H7 are associated with two pathogenic toxins released by the bacteria. These toxins were found to be identical to the toxins in bacterial dysentery. Japanese scientist Kiyoshi Shiga had identified the causal organism of bacterial dysentery in the 1890's as well as the association with bacterial toxins. *Shigella*,

²⁸ Epidemiological Notes and Reports, 1982.

²⁹ Epidemiological Notes and Reports, 1997. Editorial note to 1982 Report.

³⁰ Ibid.

³¹ Cohen, personal records on *E. coli* and juice, 1997.

the bacteria causing dysentery, “Shiga toxins”, the associated toxins, and “Stx genes”, the genes that code for Shiga toxins are all named after him. O157:H7 is only one of a large family of *E. coli* strains that are now found with Stx genes. Some of the other strains can be as harmful or deadly as O157:H7 and are referred to as pathogenic STEC (disease causing, Shiga Toxin *E. coli*). It takes more than Shiga toxins to turn *E. coli* into a potential killer, but they have to be present.

E. coli strains (serotypes) are named from immune responses to their surface characteristics (antigens). The major groups are lettered, so “O157:H7” is named for subtypes of the “O” and “H” antigen groups. O157:H7 came from a subgroup of *E. coli* mainly associated with cattle and dairy cows, causing no known bovine damage. It could be transmitted, it turned out, by almost any bird or animal including by human-to-human enteric exposure.

How did the Stx genes get from *Shigella* to *E. coli*? Research over years gradually pieced together that the transfer had been carried out by phages, virus-like infectious agents of bacteria (bacteriophages). Unlike viruses, phages can have the unfortunate ability to exist independently of bacteria in a resistant, spore-like state.

Since the medical community became aware of it in the early 1980’s, O157:H7 now is known to have a world-wide distribution, primarily in domesticated cattle and dairy cows but also in sheep, birds and other carriers. “O157:H7” is sometimes used as shorthand for the entire family of related pathogenic *E. coli*. O157:H7 is the dominant strain in North America but many other, equally dangerous strains are also present at lower frequency. Testing for O157:H7 as a specific serotype may not pick up related pathogenic STEC. Testing procedures designed for use on farms and in processing plants, or handling facilities, may test specifically for O157:H7 and miss other pathogenic STEC.

E. coli now exists as two distinct entities. The main population consists of benign, possibly useful, or mildly disease-causing strains that co-exist with humans and animals. The second population is a newly emerged, often dangerous and sometimes lethal, human pathogen. How modern agricultural practices have contributed to the evolution of the virulent populations of *E. coli* is an important and very controversial question, and an area of active research.

O157:H7 in drinking water – A review of the large-scale outbreaks

The most serious O157:H7 disease outbreaks in North America have been caused by contaminated water at single locations. The Washington County Fair outbreak in 1999 was the worst O157:H7 incident to that date, six years after the better known 1993 outbreaks traced to contaminated meat served at Jack-in-the-Box.

“On September 3, 1999, the New York State Department of Health (NYSDOH) received reports of at least 10 children hospitalized with bloody diarrhea or *Escherichia coli* O157:H7 infection in counties near Albany, New York. All of the

children had attended the Washington County Fair, which was held August 23-29, 1999.”³²

By September 15, 1999, over 921 persons were reported as ill, 65 people were hospitalized, 11 children developed HUS, and two people died. An environmental survey of the fairgrounds showed that one area of the fair’s water system was a shallow well that supplied unchlorinated water to vendors who used the water to make drinks and ice. Well water showed high levels of coliform and *E. coli*, which are primary indicators of fecal contamination.

O157:H7 was generically identified in the well and water system on September 9, 1999. Pulsed-gel electrophoresis of DNA from O157:H7 in the well, water system, and patients showed that the strain causing illness matched the DNA fingerprint of the O157:H7 in the water.³³

What contaminated the well? On March 31, 2000 the Commissioner of the New York State Department of Health made the final report on the outbreak. There were two possible contamination sources identified for the well: a dormitory’s septic system and manure from a display cattle barn. The Department refused to make a definitive judgment as to the source of the well’s contamination or if the well was the cause of the outbreak.³⁴

Another major outbreak of O157:H7 associated with drinking water occurred in May and June of 2000 when early recognition of the significance of pediatric cases of bloody diarrhea and severe abdominal cramps in Walkerton, Ontario led to a major investigation of O157:H7 illnesses. There were 1,304 reported cases, 65 patients were hospitalized, 27 developed HUS, and 6 died. The actual infection total was estimated at over 2,000. The outbreak was caused by a series of failures leading to contamination of two municipal water wells and the outbreak strain was traced back to cattle manure on a single livestock farm. The evidence suggested that the pathogens entering the wells originated with this cattle manure. According to the report by the Public Health Agency of Canada:

“A series of unfortunate circumstances occurred to cause an outbreak of this magnitude. These included heavy rains accompanied by flooding, *E. coli* O157:H7 and *Campylobacter* spp. present in the environment, a well subject to surface water contamination, and a water treatment system that may have been overwhelmed by increased turbidity. This situation emphasizes the importance of secure water sources and adequate water treatment in ensuring a safe water supply to a community. Bacterial monitoring can only identify a contaminated source after the contamination has spread through the water system and put the public at risk.

“The Walkerton outbreak calls into question the safety of ground water sources that may be under the influence of surface water, especially under flood conditions. Historically, ground water sources have been assumed to be secure and consequently

³² CDC, Morbidity and Mortality Weekly Reports, 1999.

³³ Public Health Dispatch, 1999.

³⁴ State of NY Dept. of Health, 2000.

treated with chlorination only. However, in light of this tragedy, this approach needs to be re-evaluated. Such an evaluation should take into account all current and future pressures on land use including human population density and agricultural activities.”³⁵

This was one of the better trace-backs in a series of similar incidents involving contamination of municipal or drinking water in North America.

O157:H7 in apple juice

“In the fall of 1991, an outbreak of *E. coli* O157:H7 infections in southeastern Massachusetts provided an opportunity to identify transmission by a seemingly unlikely vehicle.”³⁶ Animal transmission, particularly from beef, had dominated O157:H7 outbreaks from the time it was identified in the first four patients in 1982. This outbreak was from a small apple juice mill using traditional practices common since Colonial times



in New England. Apples were not washed and juice or cider was not pasteurized. The high acid content of apple juice was also expected to control O157:H7.

The next three O157:H7 outbreaks occurred in 1996. One was from a small Connecticut mill using brushed and washed apples, from multiple sources. Some of these were “drop” apples. Following recommendations from 1991, sodium benzoate was used as a preservative, but no pasteurization.

A small New York mill, following more of the recommendations from the 1991 case, purchased only tree-picked apples from a single orchard (drop apples went into processed or pasteurized foods from that orchard). The mill washed and brushed the apples using water from a 45 foot well. The mill was across from a dairy farm and coliform and *E. coli* were found in the well water.

In the discussion and analysis of multiple juice cases (involving different enteric pathogens) the CDC noted the likely contamination in all cases from cattle or dairy manure, either directly or indirectly, either in the orchard (dropped apples) or at the mill. “The presence of animals near a cider mill can result in manure inadvertently contacting apples, equipment, or workers' hands. In addition, apples can become contaminated if transported or stored in areas that contain manure, or if rinsed with contaminated water.”³⁷

³⁵ Public Health Agency of Canada, 2000.

³⁶ Besser, 1993.

³⁷ Outbreaks of *Escherichia coli*, 1997.

The Odwalla outbreak

The third case was the Western multi-state and Canadian outbreak due to Odwalla apple juice, October and November 1996. Cases began on October 30 and by November 9 had spread to British Columbia, California, and Colorado. Odwalla carried out a voluntary nationwide recall of all products with apple juice.³⁸ “The outbreak occurred despite sorting, washing, and brushing procedures at a sophisticated, state-of-the-art facility and despite a policy of accepting only hand-picked apples that would have been considered more than adequate in the wake of the previous apple juice-associated *E. coli* O157:H7 outbreak, which occurred in 1991.”³⁹ Seventy patients were identified as infected, 25 were hospitalized, 14 developed hemolytic uremic syndrome (HUS), and 1 died.

Odwalla was identified as the probable cause of the outbreak by a small case-control study. There was a fairly massive investigation to try and confirm the epidemiology and find the cause of the contamination. Only one unopened, recalled, juice bottle tested positive for O157:H7, out of 186 tested by the FDA, CDC, and California DHS, plus other samples in local health laboratories. That sample was indistinguishable from the outbreak strain, and both produced Shiga toxins 1 and 2. It was considered a match. Almost all of the cases could be accounted for by juice production on a single date. Three lots of apples were suspected as being the cause: two were from orchards where deer were found to carry O157:H7 and one lot contained decayed apples that had been waxed. However, *the O157:H7 found in the nine samples of deer feces did not match the outbreak strain* nor produce both toxins. The farm trace-back was a failure.

The investigation documented multiple errors in “standard procedure” at the processing plant, as well as the handler facility that shipped “waxed decayed apples.” At the processing plant they identified the following problems: there was no mechanism for enforcing a requirement for only receiving handpicked apples; and loads were supposed to be rejected if sampling showed decayed apples of 10% or more, but the procedure “was not strictly followed.”⁴⁰ Odwalla had switched from a chlorine rinse to a phosphoric acid solution, however neither of the two brands of phosphoric acid were used correctly. “According to their respective labels, one brand was not intended for use on produce and the other brand was not intended for use on waxed produce,” and one of the acids was used at concentrations below the labeled rate.

One of the implicated packinghouses sealed all apples in wax before sorting and grading, “potentially sealing in any pathogens,” and had to use three employees instead of one to remove damaged fruit from the implicated lot. The wash water was only changed once per day. Farms located near cattle admitted sending some dropped apples to this packinghouse.

At least in this report, there are no records of interviews with line employees at the Odwalla plant and the packinghouse plant, or farm workers from implicated farms, to

³⁸ Outbreaks of *Escherichia coli*, 1996.

³⁹ Cody, 1999.

⁴⁰ Outbreak of *Escherichia coli*, 1996.

gather their observations. The plant was ruled out as a contamination source because of negative swab samples, and no cases of O157:H7 reported for the vegetable and citrus juices that ran on the same lines in the same day.

Deer were not ruled out as a possible source of contamination, despite no match with the outbreak strain because: “deer, like cattle, may carry and excrete more than one strain” of O157:H7. The Odwalla outbreak is sometimes incorrectly summed up as “caused by deer.”

The Odwalla case led to increased regulation of juice, including the requirement to either pasteurize (use a kill step) or use a label with a severe consumer warning. In practice, the liability issues by themselves led many companies to pasteurize, including Odwalla. “Standard procedures at a state-of-the-art plant that produced unpasteurized juices were inadequate to eliminate contamination with *E. coli* O157:H7. This outbreak demonstrated that unpasteurized juices must be considered a potentially hazardous food and led to wide-spread changes in the fresh juice industry.”⁴¹

The juice cases show that small size and traditional processing methods, or large size and (then) state-of-the-art methods, are both susceptible to O157:H7 contamination. They also show in the Odwalla case, that despite being the largest fresh juice processor in the U.S., *quality standards enforcement for accepting fruit, and standards imposed on handlers by themselves, might have prevented the outbreak.*

O157:H7 in sprouts

One of the largest worldwide outbreaks of O157:H7 occurred in Sakai City, Osaka prefecture, Japan, in 1996. Reported infections reached over 10,120 cases and included 12 deaths. In one large cluster, 6,000 of the cases were school children. Mass foodservice of regional school lunches contributed to the large scale of the outbreak.

Although there was no effective trace-back or epidemiological evidence, and no reported case control study, the outbreaks were attributed to white radish sprouts grown at a single hydroponic facility and then blamed on seed grown on an Oregon farm. The assignment to radish sprouts and the blaming of Oregon radish seed production were never documented in any manner and the author’s discussions with the Japanese Embassy at the time indicated that there were political reasons for naming sprouts rather than other food items in the lunches. There were strong political overtones, including decisions by the Health Minister who became head of the Democratic Party. The government was ordered to pay redress to sprout growers, upheld at the Osaka Prefecture high level court in 2004. This judgement appears to still be on appeal at the Tokyo (national) level of the courts.⁴² These developments show the wisdom of discretion in assigning causal blame as shown in two other cases discussed here (NY State Health Commissioner and CALFERT), a discretion not practiced in Japanese outbreaks.

⁴¹ Cody, 1999.

⁴² Imamura, T., 2007; “Kaiware” farmers sue state...”, 1997; “Farmers win redress...”, 2003; and “Court upholds redress...”, 2004.

Regardless of the cause of the problem, the research that followed turned out to be critical to the sprouting and fresh cut industries. A team led by Yoshinori Itoh proved that radish sprouts grown in O157:H7 inoculated media could internalize bacteria in plant tissue.⁴³ The sprout cases led to increasing research on the issue of internalization of pathogens into plant tissue and to increased human pathogen testing for seeds in fresh-cut production. The research into seeds used to grow sprouts has shown conclusively that “seeds used in sprout production are the likely source of contamination in most outbreaks.”⁴⁴

Most of the approximately thirty food-borne sprout outbreaks in the ten years since 1997 were due to *Salmonella* on alfalfa sprouts, with a secondary peak of *Salmonella* on mung bean sprouts. There was only one major outbreak due to O157:H7 on alfalfa sprouts. In this case, “In June and July 1997, simultaneous outbreaks of *Escherichia coli* O157:H7 infection in Michigan and Virginia were independently associated with eating alfalfa sprouts grown from the same seed lot,” which led to investigation of mechanisms of alfalfa seed contamination.⁴⁵

Later investigation showed a secondary cluster of cases caused by human re-transmission of the outbreak strain. “This outbreak shows how food-borne outbreaks can extend in a community. The identification of an identical PFGE [pulsed field gel electrophoresis] pattern in a second cluster of patients at the end of the outbreak suggests that a lake was contaminated by feces from an infected patient. Such contamination is possible because *E. coli* O157:H7 can survive for weeks in lake water and has a very low infectious dose.”⁴⁶

Seed production fields can become contaminated by *Salmonella* or O157:H7 before harvest, at harvest, or in handling and storage. One report showed that the single most important factor for reducing risk of seed transmission was to have the highest percentage of undamaged seeds.⁴⁷ No seed treatments acceptable for food processing have been found to be completely effective in preventing pathogens from reproducing and increasing to disease-causing levels, in the warm, humid conditions used for sprout production.

⁴³ Itoh, 1998.

⁴⁴ CFSAN, 2004.

⁴⁵ Outbreaks of *Escherichia coli*, Aug. 1997.

⁴⁶ Breuer, 2001.

⁴⁷ Rajkowski, 2005.

III. O157:H7 on California Leafy Greens Before the September 2006 Spinach Outbreak

The following table lists all of the E. coli O157:H7 outbreaks known to the FDA and traced to California leafy greens during the period 1996 through 2005.⁴⁸ This table only lists the outbreaks prior to the spinach outbreak of 2006, but it shows that the majority of the 12 outbreaks were traced to the fresh cut industry.

Table 3: 1996-2005 E. Coli Outbreaks Associated with California Leafy Greens

Date	Number of patients	Type of leafy green	Source location
May 1996	61	Mesclun mix lettuce	Salinas Valley
September 1999	8	Romaine lettuce*	Salinas Valley
September 1999	6	Lettuce*	Salinas Valley
October 1999	3	Romaine hearts	Salinas Valley
October 1999	41	Fresh cut Romaine	Salinas Valley
July 2002	29	Fresh cut Romaine	Salinas Valley
November 2002	24	Iceberg lettuce, Fresh cut	Lemoore, CA
September 2003	27	Lettuce mix with romaine, Fresh cut	Salinas Valley
September 2003	5	Fresh cut Lettuce mix with romaine	CA
October 2003	16	Fresh cut spinach	Salinas Valley
November 2004	6	Fresh cut Lettuce	CA
September 2005	32	Fresh cut Salad	Salinas Valley

* fresh-cut or whole-fresh unknown

Prior to the 2006 spinach outbreak, the FDA had expressed increasing concern about the number of fresh produce outbreaks on lettuce, in particular, and leafy greens in general from California.

⁴⁸ Combined data from CAFF analysis of FDA data; the Minnesota Department of Health presentation on the Taco John outbreak (Meyer, 2007); and Cohen email communication with Jack Guzewich, Acting Director of FDA/CFSAN division of Public Health and Biostatistics. The data sets were compatible and supplemented each other. Lettuce hearts are included in fresh-cut. None of the outbreak and investigation reports for the above table could be clearly identified and accessed.

- The FDA issued a *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, in October 1998.⁴⁹
- On Feb 05, 2004 the FDA published a *Letter to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes*. “This letter is intended to make you aware of the Food and Drug Administration's (FDA's) concern regarding continuing outbreaks of food-borne illness associated with the consumption of fresh lettuce and fresh tomatoes, and actions we recommend that your industries take to enhance the safety of these products... 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.”⁵⁰
- In October 2004, the FDA issued *Produce Safety From Production to Consumption: 2004 Action Plan to Minimize Food-borne Illness Associated with Fresh Produce Consumption*.
- On April 25, 2006 a fresh produce industry coalition put out the first edition of *Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain*. This is also listed under produce safety at the FDA website. The industry groups were the International Fresh-cut Produce Association, the Produce Marketing Association, the United Fresh Fruit and Vegetable Association and Western Growers. It became the starting point for the Leafy Green GAPs (Good Agricultural Practices) or metrics in 2007.⁵¹
- On August 23, 2006, just before the Dole spinach outbreak and recall, the FDA announced a *Lettuce Safety Initiative*: “The Food and Drug Administration (FDA) developed the Lettuce Safety Initiative as a response to the recurring outbreaks of *E. coli* O157:H7 associated with fresh and fresh-cut lettuce... The Initiative will begin with this fall's lettuce harvest season. A majority of the outbreaks traced product back to California... FDA will continue to coordinate and closely collaborate with the State of California's Department of Health Services and Department of Food and Agriculture.”⁵²

⁴⁹ US FDA 1998.

⁵⁰ US FDA, 2004.

⁵¹ International Fresh-Cut Produce Association, 2006.

⁵² US FDA, 2006.

IV. The 2006 Dole Fresh-Cut, Bagged, Baby-Spinach Outbreak

Here are excerpts from two of the official reports on the September 2006 spinach outbreak:

“On September 13, 2006, CDC officials were alerted by epidemiologists in Wisconsin and Oregon that fresh spinach was the suspected source of small clusters of *Escherichia coli* serotype O157:H7 infections in those states. On the same day, New Mexico epidemiologists contacted Wisconsin and Oregon epidemiologists about a cluster of *E. coli* O157:H7 infections in New Mexico associated with fresh spinach consumption. Wisconsin public health officials had first reported a cluster of *E. coli* O157:H7 infections to CDC on September 8.

“On September 12, CDC PulseNet had confirmed that the *E. coli* O157:H7 strains from infected patients in Wisconsin had matching pulsed-field gel electrophoresis (PFGE) patterns and identified the same pattern in patient isolates from other states.”⁵³

“On the afternoon of September 13, CDC informed FDA of a multi-state foodborne illness outbreak that appeared to be ongoing, of *E. coli* O157:H7 possibly associated with the consumption of fresh spinach. On September 14, CDC notified FDA that the epidemiological data confirmed that fresh spinach was implicated as the source of the illnesses.”⁵⁴

The outbreak, defined as continuing reporting of new illnesses due to the outbreak strain, lasted a month. CDC’s last update was on October 6, 2007. They reported a cumulative total of 199 infected persons in 26 states, 102 were hospitalized and 31 had developed HUS. Three deaths were confirmed. The outbreak strain was considered highly virulent because of the 50% hospitalization rate and 15% HUS rate. The peak of onset of illness had occurred on August 30, August 31, and September 1. Most people were becoming ill 10 days or more before the first warnings.



“It became clear early on from interviews with ill persons that consumption of fresh spinach during the week prior to onset of illness was a feature shared by the vast majority of cases. In fact on September 14 -- one day after the outbreak was formally identified -- fresh spinach was implicated as the cause of the outbreak.”⁵⁵

A special questionnaire was used for spinach consumption that narrowed the type of spinach down to fresh spinach, eaten raw, from a pre-packaged bag, or at home.

⁵³ Ongoing Multi-State Outbreak, 2006.

⁵⁴ Bracket, R.E. CFSAN Director, Senate testimony, 2006.

⁵⁵ CDC, 21 Sept. 2006.

The Odwalla investigation had found only one bottle with an outbreak strain out of hundreds sampled. The spinach investigators, in multiple states, managed to find 44 bagged spinach samples in patients' homes and started using UPC codes to trace processors. Natural Selection Foods had manufactured 37 of the collected bags. Using the product UPC codes, a trace-back could be conducted, leading to the source spinach processing plant and, eventually, the source fields. A trace-forward could identify where product had gone from the processing plant.

According to the COCA (Clinician Outreach and Communication Activity) conference call transcript a key confirmation came on September 20. "On September 20th, New Mexico's public health laboratory announced it had isolated the outbreak's strain of *E. coli* O157:H7 from an open package of spinach that came from a refrigerator of a patient who had eaten some of the spinach before becoming ill. The package of spinach that tested positive was Dole baby spinach, best if used by August 30." Spinach from 13 bags was eventually found to be positive for O157:H7. The O157:H7 strain in all 13 was a genetic match to the outbreak strain. All were a subset of the Natural Selections Foods manufactured bags. All 13 were Dole brand Baby Spinach manufactured by Natural Selection Foods at a facility in San Juan Bautista.

Piecing together the timeline, it looks like there was good reason to suspect bagged spinach from the beginning of the federal involvement. Natural Selection Foods was the most likely processor, but the collected spinach bags had a range of dates and not all were from NS Foods. It was not until September 20th that they could narrow the outbreak strain to the Dole bags, which all had the same product code, prefix "P227A," which corresponded to a single date. The September 2006 "Dole Spinach Outbreak" was in fact confined to just fresh-cut baby leaf spinach.

Public warnings, recalls and updates

On September 14, FDA News released *FDA Warning on Serious E. coli O157:H7 Outbreak: One Death and Multiple Hospitalizations in Several States*.⁵⁶ The initial warning mentioned "all fresh produce" and preliminary evidence suggesting bagged spinach as the cause. On the same day CDC issued an official *CDC Health Alert*,⁵⁷ but only mentioned "FDA advises consumers not eat bagged fresh spinach at this time."

On September 17, the FDA released *FDA Statement on Food-borne E. coli O157:H7 Outbreak in Spinach*.⁵⁸ Now the warning was associated with all raw spinach, not just bagged raw spinach. "Based on current information, FDA advises that people not eat fresh spinach or fresh spinach-containing products that are consumed raw. Individuals who believe they may have experienced symptoms of illness after consuming pre-packaged spinach are urged to contact their health care provider."

⁵⁶ US FDA, 14 Sept. 2006.

⁵⁷ CDC, 14 Sept. 2006.

⁵⁸ US FDA, 17 Sept. 2006.

Also: "At this time, Natural Selection Foods, LLC, of San Juan Bautista, California, is recalling all of its products that contain spinach in all the brands they pack with 'Best-if Used-by-Dates' of August 17, 2006 through October 1, 2006." Thirty brands were listed.

A trace-back to Natural Selection Foods' processing plant in the Salinas Valley had taken about a day, but the exact best used by dates were not known. It apparently was not clear if some product, possibly contaminated, had entered the whole fresh food chain, or how far product might have traveled and commingled in the complex produce distribution system, perhaps to other fresh-cut processors. The trace-forward could not be exact.

By September 17th there had been 109 cases, 16 with HUS and one death. The FDA mentioned its "Lettuce Safety Initiative" had been expanded to include spinach. "Leafy Greens" as a category began to take shape.

On the 18th, any distinction between bagged and whole spinach was dropped: "*FDA advises consumers not to eat fresh spinach or fresh spinach-containing products until further notice.*" As a result, an ambiguous trace-forward shut down nearly the entire spinach market in the United States,⁵⁹ causing economic disruptions to growers not growing for the fresh-cut market.

On September 20th, the FDA had to issue a reminder that traditional food processing of spinach was still safe: "At this time, FDA has no evidence that frozen spinach, canned spinach and spinach included in pre-made meals manufactured by food companies are affected. These products are safe to eat."⁶⁰

By October 4, the medical aspects of the outbreak were ending and the aftermath was beginning. The U.S. Department of Justice released a *Statement on Spinach Searches*: "The US Attorney's Office for the Northern District of California announced that agents of the FBI and FDA Office of Criminal Investigations executed two search warrants today on Growers Express in Salinas, CA, and Natural Selection Foods in San Juan Bautista, CA, in connection with the September 2006 outbreak of *E. coli* O157:H7 that the FDA has traced to spinach grown in the Salinas area."⁶¹ No criminal charges were subsequently filed.

After brief consideration of patient numbers, the FDA's announcement on October 6 focused on "Next Steps": "There has been a long history of *E. coli* O157:H7 outbreaks involving leafy greens from the central California region... FDA and the State of California have previously expressed serious concern with the continuing outbreaks of food-borne illness associated with the consumption of fresh and fresh-cut lettuce and other leafy greens. After discussions with industry, FDA and the State of California...now expect industry to develop a plan to minimize the risk of another outbreak due to *E. coli* O157:H7 in all leafy greens, including lettuce."⁶²

⁵⁹ CDC, 18 Sept. 2006.

⁶⁰ CDC, 20 Sept. 2006.

⁶¹ Ryan, K.V. 2006.

⁶² US FDA, 06 Oct. 2006.

The Grower Shipper Association of Central California, the Produce Marketing Association, the United Fresh Produce Association, and the Western Growers Association, all were mentioned as agreeing to cooperate in developing new safety plans.

The FDA warned: "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." The produce industry's approach to regulating food safety was almost mandated by the position outlined in the FDA Statement. This included covering all "leafy greens" and not differentiating fresh-cut as a separate industry.

CDC and FDA moved on to the Taco Bell and Taco John O157:H7 outbreaks of December 2006. These eventually traced back to two different contamination events on fresh-cut food service lettuce. One of the lettuce outbreak strains traced back to a production field near a dairy farm carrying the same strain.

Information on how the Dole spinach got contaminated would seem critical to any "next step," but the outbreak investigation report was not released until the end of March 2007.⁶³

Investigation of the outbreak

The investigation of the 2006 O157:H7 Dole spinach outbreak was probably the best investigation carried out to date, and is considered a model for future investigations. It was conducted by the San Francisco office of the FDA and the California Department of Health Services under a joint program called the California Food Emergency Response Team (CalFERT), with aid from many other agencies including UC Davis. CalFERT had a training exercise going on in the Salinas Valley at the time of the outbreak that was converted into an active investigation.

Using CDC data from the outbreak, they were able to trace the illness-associated spinach bags to a single production shift on August 15, 2006, at the "South" plant, one of two plants producing for a single company, Natural Selection Foods (NSF), which was processing Dole brand baby spinach with product code beginning P227A.

The investigation covered: (1) the NSF processing facility, including process flow and product coding/traceability; (2) harvester investigations of four companies; (3) field investigations; and (4) third party laboratory techniques.

CalFERT was able to trace the source of spinach to four fields on different farms, and then to rule out three farms that did not match the outbreak strain of O157:H7 in the farm environment. O157:H7 strains were identified by PFGE (pulsed field gel electrophoresis) of bacterial DNA. By this test definition the outbreak strain was found in 15 samples of cattle feces, 8 samples of wild pig feces, one sample of pasture soil/dust, and 5 samples

⁶³ California Food Emergency Response Team, 2007.

from the San Benito river or creeks; all from locations in the environment surrounding the suspect field.

This was a 50.9-acre field ("Lot 1") that was part of a small production area leased by Mission Organics on the Paicines Ranch, which mainly raises cattle. The field was in transition to organic production. No practices involved in transition to organic were implicated. The investigations of the implicated fields took place between September 20 and November 29.

There were high levels of O157:H7 that did not match the outbreak strain in both cattle and pig feces. No (soil or plant) samples from the implicated spinach field were positive for any strain of O157:H7 at the time of investigation.

The investigators did *not* find O157:H7 of any kind in feces samples tested for coyote, deer, dog, horse, small ruminants, small water fowl, unknowns, or owl pellets. Nor was any found in other kinds of environmental samples including aerosols from pastures or fields, plants, pasture pond sediment, small reservoir sediment, wells, chicken pellet compost, cattle water troughs, a water reservoir, multiple wells or other water sources *other than* the San Benito river and creeks.

"CALfert investigators examined the spinach washing, processing and packaging process at NSF and collected finished product and environmental samples. No *E. coli* O157:H7 was identified at the processing facility. However, a number of conditions were observed that may have provided opportunities for the spread of pathogens..."⁶⁴

The investigators worked closely with NSF managers to reconstruct the actual operations methods and the document trail that could be shown, what the standard operating procedures were, and what the records were of them being followed.

In the *Summary of Observations* the report notes: (1) safety procedures used at NSF original plant were not customized for the South plant's conditions; (2) during the production week from August 14 - 19 the South facility had the highest volume of the month; (3) during the same time period the plant had a string of personnel shortages; including (4) 9 absent employees on August 13, the extended sanitation shift before the outbreak production date; (5) a number of workers were absent due to illness or family illness, without documentation of the kind of illness; (6) "the parameter recorded as turbidity and used to determine the frequency of water changes was actually a measure of water color" and no validation of that method was shown; and (7) there were no records of the field totes used for bringing in spinach being washed on August 15, although there were for August 1- August 14. There were no records of the larger bins being washed at all.

⁶⁴ Ibid.

Most public attention was focused on which farm or fields were “the source of the outbreak”—since there had been announcements that an individual field had been identified—and how the spinach had been contaminated in that field. As in the Odwalla outbreak, wild animals became the culprit in many press reports.

There was only one conclusion made in the report. It reads exactly like the conclusion of the New York State Public Health Commissioner in 1995 after the Washington County Fair outbreak:

“No definitive determination could be made regarding how E coli O157 pathogens contaminated spinach in this outbreak.”⁶⁵

The politics of the investigation report

The political battle over food safety regulation began the moment the CalFERT investigation was completed and before their report was released.

In testimony before the California Senate in February 2007, DHS officials noted that the investigation was completed in 2006, and the report was expected to be released in the first week of January 2007. There were disagreements between the San Francisco FDA office and DHS over the language of the report and the data that should be included.

Investigation of an Eschericia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach was published as a final redacted report on March 23, 2007 (but dated March 21, 2007). A correction to the report was published as an *Addendum* on May 7, 2007.⁶⁶ Part of the reason for the correction appears to be the reaction of ranchers, landowners or farmers of the traced back spinach fields to the negotiated language of the investigation report. One key paragraph in the Addendum reads:

“The final sentence on page 3 refers to the presence of wild pigs ‘**in and around spinach fields.**’ This sentence was not intended to indicate that wild pig tracks were observed in the implicated 50.9 acre lot (lot 1) on Paicines Ranch. Investigators observed wild pig tracks in fields and on dirt roads approximately 1 mile south of lot 1.”

Lot 1, Paicines Ranch is the implicated source of the spinach which created the outbreak, because of neighboring environmental contamination with the outbreak strain. It is the main spinach field discussed in the report.

A further correction on May 7 was:

“In the first paragraph on page 30...the report incorrectly stated that wild pig tracks were observed ‘**through prepared beds in lot 1**’ and suggested that pigs were

⁶⁵ Ibid.

⁶⁶ Ibid, with corrections.

crossing from the riparian areas through the fields ‘to the vineyards on the far side of lot 1.’ No pig tracks were observed by the investigators in lot 1... [and] it would not have been necessary for the pigs to traverse lot 1 to reach these vineyards.”

It is uncertain how the spinach was contaminated, or even if it was contaminated in the field. The story that the 2006 Dole spinach outbreak was due to pigs was widely circulated and is still common, despite the little-noticed corrections. Any story that proposed a mechanism for field contamination also reinforced the idea that growers and their farms were the sole issue in fresh-cut leafy green safety.

The FDA and California DHS intended to have the leafy green industry, based in Salinas, come up with its own food safety response plan, as discussed in the FDA’s October 6, 2006 outbreak update. With great internal controversy, between October 2006 and February 2007, this became the California Leafy Green Marketing Agreement (LGMA)⁶⁷ supported by the California Dept. of Food and Agriculture (CDFA).

An additional buyers-led food safety initiative put great pressure on the leafy green industry. The history of this initiative can be found on Jim Prevor’s web-site *The Perishable Pundit*, January 22, 2007. Initial signatories included Safeway, Wegman’s, Supervalu, Kroger, Sysco, Denny’s, Costco, Amerifresh, and Markon. By January 22 they had been joined by Publix, Pathmark, Food Lion, Raley’s, Wild Oats and others. They intended to set their own safety standards as the customers of the leafy green processors and handlers, which they could do via business contracts.

California State Senator Dean Florez introduced legislation on February 7, 2007,⁶⁸ that would put control of leafy greens and produce safety under the Department of Health Services instead of the industry and CDFA. Positions on leafy green food safety were made clear at the California Joint Assembly and Senate Committees on Agriculture *Informational Hearing on Farming and the Environment: An Overview of the 2006 E. coli Outbreak*, February 27, 2007.⁶⁹

Each of these three approaches (LGMA, buyers, or legislation) has been problematic. The LGMA plan was to use the 1937 California Marketing Act to regulate food safety on farms through Marketing Agreements (voluntary) and Marketing Orders (compulsory). Next they planned to use parallel State acts in Arizona and other states and comparable laws in Mexico, if possible. Finally, they intended to set up federal Orders and Agreements under the original U.S. 1937 Marketing Agreement Act that would be administered under the authority of the USDA.

The plan was outlined by the Western Growers Association and the California Farm Bureau in testimony at the Joint Committees hearing in February 2007:

⁶⁷ CDFA, www.caleafygreens.ca.gov

⁶⁸ California Senate Bills 200, 201 and 202.

⁶⁹ Joint Assembly and Senate Agriculture Committees, Feb. 2007.

- A California Leafy Green Marketing Agreement (voluntary, representing handlers and processors, under CDFA)
- A California Leafy Green Marketing Order (compulsory, representing handlers or growers, under CDFA)
- A Federal Leafy Green Marketing Agreement (voluntary, handlers and processors, under USDA)
- A Federal Leafy Green Marketing Order (compulsory, handlers or growers, under USDA)
- While the Federal actions were being taken, replicate and coordinate the State Agreements and Orders in other states starting with Arizona and if possible come to similar arrangements with Mexican states producing leafy greens.

The California LGMA was established, funded and operating by July 2007. The Arizona marketing agreement was established in October 2007.⁷⁰ Attempts were made to change the federal Marketing Act to accommodate farm food safety as part of the 2007 farm bill. On October 4, 2007 the USDA Agricultural Marketing Service (AMS) published an advance notice of proposed rulemaking in the Federal Register entitled: *Handling Regulations for Leafy Greens under the Agricultural Marketing Agreement Act of 1937* which could lead to either an order or an agreement.

Produce buyers' reaction to the Dole outbreak was also swift and had a direct impact in the Salinas Valley because of their ability to specify food safety procedures, both on-farm and in processing, through purchasing conditions in their contracts. Their approaches were mirrored in the LGMA's rules as these came to be applied later in 2007. The practical result on-farm was that in order to achieve fresh-cut "food safety," farmers were told that production fields had to be protected from the environment around them through habitat removal. Significant environmental disruption became a byproduct of the production of supposedly *healthy, convenient salads*.

⁷⁰ Arizona Dept. of Ag. 2007.

V. On-Farm Impacts of the New Regulations

The Monterey County Resource Conservation District (RCD) released a survey in August 2007⁷¹ that summarized the problem as follows:

“The efforts of agricultural producers on the Central Coast and throughout the state to protect water quality and the environment may be compromised as some food safety guidelines, or interpretation thereof, appear to be in conflict with management practices intended to improve water quality and enhance natural habitat. Growers of fresh produce, particularly leafy greens, are caught in the middle between these competing priorities and in many cases are being put in a position of having to choose between being able to sell their crops or protect the environment.”

Farmers reported auditors rejecting fields for deer tracks, deer intrusion, proximity to horse pens, potential frog habitat, snails, mice, and buffers less than 100 feet from trees. Farmers have been asked to remove non-crop vegetation, ponds or other water bodies and wildlife. They have actually removed (or plan to remove) ponds, irrigation reservoirs, duck habitat, tailwater recovery systems, grassed waterways, filter/buffer strips near water, trees and shrubs. In order to discourage wildlife they have used bare ground buffers (or other non-vegetable crops), fencing, trapping and poisoned bait.

The RCD analysis showed greater removal of environmental practices for conventional growers selling to shipper/packers. Comments from growers showed concern that there was going to be much greater impact over time, and that they were in a double bind because in order to sell their produce they would end up being liable for the ground and water pollution that their (now eliminated) environmental practices had been protecting against. The growers wanted to support wildlife and provide habitats, not discourage wildlife. They also questioned the scientific validity of the practices the shipper/packers, buyers' agents, and the LGMA were imposing.

CAFF has had projects in the Salinas Valley and Central Coast for over twenty years, working with growers of all farm sizes to improve farm habitats and water quality through hedgerows, filter strips, riparian plantings, native plants, cover cropping and other methods that allow farms to be a benefit to the environment and the natural environment to be a benefit to farms.

CAFF's experience after the 2006 spinach outbreak is consistent with the Monterey County RCD report. Damage to the farm environment due to food safety metrics, and buyer or third party ratings of fields has gotten worse since the time of the survey. Some buyers are telling growers not to use compost of any kind, regardless of how it is produced, what it is made from or if it has been microbiologically tested. Farmers are removing hedgerows and trees and poisoning rodents (which can kill the birds that eat the rodents) and frogs. Certain contracts for hedgerows and other environmental plantings have been cancelled. Fencing against deer, pigs, frogs or human entry into fields is

⁷¹ Resource Conservation District, 2007.

increasing. Fencing near roads, streams, or populated areas can conflict with county or city zoning ordinances, and an increasing number of variances are being applied for.

The significance of the loss of environmental stewardship practices, in terms of water quality as well as wildlife, was discussed, analyzed and illustrated in a UC Santa Cruz report.⁷² The authors clearly recognized the extent of the potential conflict with food safety as soon as the 2006 spinach outbreak occurred.⁷³

“Central Coast growers face regulatory mandates to limit pollution originating from fertilizers, pesticides, and erosion sources. Coalitions of growers, government, and non-governmental organizations have worked hard to put in place ‘best management practices’ using non-crop vegetation such as filter strips, vegetative barriers, contour buffer strips, grassed waterways, and constructed wetlands designed to minimize the impacts of agricultural pollutants on adjacent waterways and wetlands.

“The watersheds of the region, including those of the Pajaro River, the Salinas River and Elkhorn Slough, empty into the Monterey Bay National Marine Sanctuary, the largest marine protected area in the United States. Elkhorn Slough is also one of the largest remaining tidal wetlands in the US...”

Non-crop vegetation can be designed to prevent a point source of pollution (including manure) from spreading, or to protect rivers and waterways from absorbing runoff of fertilizer, pesticides, or sediment. It also provides natural habitat for wildlife, which in other situations is considered a benefit.

The UC Santa Cruz report makes the case that environmental practices could be designed to reduce pathogens in the farm environments by reducing pathogen loads in water sources, as is already done in wastewater systems for municipalities. However, the long-term reduction of sources of pathogens in the farm environment has never been an objective of the farm food-safety procedures. The metrics are designed to prevent pathogen carriers from entering production fields and contaminating crops.

Buyers’ food safety rules after the spinach outbreak

Buyers’ rules for farmers are sometimes conveyed orally or, if written, are confidential. The major reasons that the buyers require habitat removal are to prevent animal intrusion into fields and to remove water sources that could attract animals.

In the CalFERT report on the 2006 spinach outbreak, only cattle and pigs were associated with O157:H7 of any kind. A long list of (larger) animals were not shown to be contaminated including deer, coyotes, dogs, horses, small ruminants, waterfowl etc. Nonetheless, all of these are now considered potential sources of *Salmonella* and O157:H7, no matter what the actual probability of contamination.⁷⁴

⁷² Stuart, 2006.

⁷³ In fact, the principal author was working for NRCS at the time.

⁷⁴ A description of the general farm food safety rules for Fresh Express prior to the spinach outbreak was published in October 2006 in USA Today (Schmit, 2006).

The net impact of the buyers' rules (for leafy greens and in more recently published rules, all produce) can be simplified to:

1. If it moves, exclude it from fields.
2. If there is a habitat for something that moves, for example a tree, remove it or lose part of the field.
3. Don't plant near habitat (for example, calling for 100-900 foot buffers).
4. If there is a known higher probability source of pathogens, don't plant within one mile (or some other metric, greatly exceeding the LGMA distance recommendations).
5. Try to protect water sources in a similar manner to fields, or remove them.
6. If any input on a farm could be a pathogen source (including seeds) treat it to remove pathogens, test it for being pathogen-free, or don't use it.
7. If any organism or input is reported in the scientific literature as a potential pathogen carrier, treat it as a potential transmitter to crops—guilty until proven innocent.

Field margins are supposed to be protected by fencing above ground to exclude large animals, fencing below ground to exclude burrowing animals, and by frequent poisoned bait stations to exclude small animals that can climb or otherwise get through the fencing. The buyers' rules can be seen as primary tools to prevent crop contamination by animal manure or feces that could carry the human enteric pathogens, such as O157:H7 and *Salmonella*, which have caused the fresh-cut outbreaks.

In September 2007 a group of buyers including Avendra LLC, Darden Restaurants, McDonald's Corporation, Publix Super Markets, Wal-Mart Stores, Inc., and Walt Disney Company published their own rules, generic to all produce, the "Food Safety Leadership Council On-Farm Produce Standards."⁷⁵ In addition to covering the generally expected topics, the document contains a section on "Food Defense," in which they admonish the grower:

"Effective measures are taken to control unauthorized access to facility and/or field. Measures can include cameras, employee identification, fences with locked gates, security guards, area patrol, unauthorized entry signs, etc.

"Access to all areas is restricted to authorized personnel only. Visitor entrances are clearly posted and visitor access, including of duty employees, is strictly controlled. Visitors, including contractors and regulatory inspectors, are logged in, provided with identification badges and accompanied by appropriate personnel at all times. Visitors should be given a copy of GAPs and/or GMPs to review."

There are many large conventional growers of leafy greens in the Salinas Valley and Central Coast who would rather not have to choose between economic survival (with locked and gated farm fields) and environmental practices. There also are growers of all sizes for whom environmentally compatible farming is their way of life or integral to their production methods and decisions.

⁷⁵ Prevor, J., 13 Nov. 2007.

These growers can be seen as squeezed between conflicting governmental regulations: “Best management practices” that help them meet environmental requirements to reduce pollution run-off from farms, are at odds with “good agricultural practices” for food safety that treat non-crop vegetation as habitat for disease carriers, from frogs to hogs.

The contamination of the farm environment by human pathogens cannot be solved using field-by-field, farm-by-farm, crop-by-crop regulations and buyers’ rules that are ultimately paid for by growers and also cause environmental degradation. The metrics, GAPs, and customized buyers’ field ratings may simply succeed in destroying habitats and damaging farmers and their market identity, without improving fresh-cut produce safety.

VI. The Politics of Farm Food Safety Regulation

Leafy-green growers throughout the United States face the following problematic choices in being regulated for farm-food safety:

1. Regulation controlled by 4 or 5 processors through handler /processor-created Marketing Act Agreements and Orders.⁷⁶
2. Regulation controlled by less than 150 of the largest California and Arizona growers through farmer-created Marketing Act Agreements and Orders.
3. Regulation controlled by a centralized federal or state bureaucracy such as FDA or USDA, designed for the 2% of the largest farmers who grow for fresh-cut, but applied to every farm.

Finally, there are also the metrics enforced by the buyers, without public oversight, that may go well above and beyond the regulations adopted by a more public and formal process.

Most food-safety approaches are designed on a crop-by-crop basis. There are programs for leafy greens, tomatoes, apples, melons, almonds and other crops. To achieve food safety, legal, state and governmental controls for each crop affect an entire farm operation. Individual farms that grow more than one crop could be subject to multiple, complex regulations that can be very difficult to reconcile.⁷⁷

Most of the approaches also reflect the concentrated economic power of the largest growers, processors, or buyers. Among the largest buyers is the federal government itself, which regulates farming practice through General Service Administration (GSA) acquisition rules on food suppliers.

Finally, all of the food safety approaches to date, impose controls designed for approximately 2% of the largest fresh-cut farmers, on all farmers of a crop. Instead, these regulations should address the special safety requirements of the fresh-cut processing industry.

Using marketing orders and agreements to regulate on-farm practices

Marketing Act Orders (mandatory) and Agreements (voluntary) at their best are an awkward and inappropriate tool for farm food-safety. The California LGMA (Leafy Green Marketing Agreement) can be seen as an emergency response to the Dole fresh-cut baby spinach outbreak. The emergency, however, was that the industry had reached the end of legislators', regulators', and buyers' patience after years of outbreaks and warnings. The FDA's extraordinary step of including a specific warning to industry that

⁷⁶ For example, the California Marketing Act of 1937.

⁷⁷ In our comparison of LGMA metrics with Food Safety Leadership Council metrics we found different microbiological acceptance criteria for soil amendments and for irrigation water; different classification systems for fertilizers and irrigation water; differences in the buffer requirements for animals; and many other differences that could potentially be difficult to reconcile.

something was going to be done about regulation as part of the outbreak-update on October 6, 2006 meant that either the industry responded or it would no longer have any control over its own practices and fate.

The shutdown of the entire spinach market in the United States made it clear that fresh-cut industry competitors could all suffer from an outbreak eventually traced to a specific plant and location. It also meant that the whole-fresh market was at the mercy of errors in fresh-cut. However, the industry's regulatory attention was shifted solely to the problem of contamination on-farm. In California they were fully supported in this approach by both the agriculture and health departments—CDFA and DHS.

This helps to explain the extraordinary structure of the LGMA, a (voluntary) processor and handler Agreement whose main purpose is to regulate on-farm production practices of growers, using documented good agricultural practices (GAPs or metrics) as the selection criteria all processors or handlers have to use.

The Arizona Department of Agriculture (ADA) issued a press release on October 4, 2007 announcing the October 2, 2007 approval of the creation of the Arizona Leafy Green Products Shipper Marketing Agreement, a voluntary program for shippers to assure food safety of leafy greens. As stated in their press release:

“The marketing agreement was initiated by two Arizona leafy green shippers interested in implementing measures to further assure safety of their products... During the twenty-two day initial sign up period that ended on September 27th, 2007, thirty-two shippers signed up for the agreement, which constitutes approximately 75-85% of all leafy greens produced in Arizona. Additional shippers may voluntarily join but once in the agreement they will be subject to mandatory compliance with the adopted safety procedures and inspections.”⁷⁸

At the federal level, the Agricultural Marketing Service (AMS) of the USDA published its Advanced Notice of Proposed Rulemaking on October 4, 2007. Handling Regulations for Leafy Greens under the Agricultural Marketing Agreement Act of 1937 is the first regulatory step needed: “...in response to industry interest in the establishment of a marketing program to address the handling of fresh and fresh-cut leafy green vegetables. The program would allow packers, processors, shippers, and marketers (collectively referred to as handlers) to maintain the quality of their products by reducing the risk of pathogenic contamination during the production and handling of leafy greens.”

CAFF does not believe Marketing Act programs are well suited for regulating on-farm produce food safety for the following reasons:

1. Marketing Act programs give control to a small group of the largest processors or growers.

⁷⁸ Arizona Dept. of Agriculture, 2007.

The Marketing Acts allow establishment by vote proportional to the dollar value of production. Thus, the largest handlers or growers subject every farmer who grows a crop regulated by a Marketing Act program to State or Federal police powers control. Because of the very high concentration of production, a few large and very large growers can control farmer Agreements and Orders, and a handful of processors can control handler/processor Agreements and Orders.

2. Marketing Act programs can give handlers and buyers control over on-farm production practices.

The California LGMA demonstrates this problem. Illustrating where this structure might lead are the metrics going far beyond the LGMA, imposed by handlers in Salinas. Some of their requirements are impractical, ineffective, unscientific and at odds with environmental stewardship.

3. Marketing Act programs and other leafy greens food safety approaches have not distinguished between fresh-cut and whole produce.

The fresh-cut processing industry is responsible for the majority of multi-state outbreaks or recalls due to contamination with pathogens. But the overwhelming majority of growers, over 98%, grow for the whole fresh market. These traditional growers would be controlled by the 2% who have been associated with outbreaks, or by the processors who, as a group, have also been implicated.

4. The crop-by-crop nature of the Marketing Acts doesn't work well for farms growing more than one crop.

The Marketing Acts were not designed for farm food safety and when food safety is forced into their structure, it has to follow a crop-by-crop approach. Any farmer who grows one of the covered crops will have to change his entire farm in order to comply with the rules for one crop, even if that crop is a minor part of the overall farm production. A grower of multiple crops such as lettuce, carrots, tomatoes, broccoli, cauliflower, onions, squash, pumpkins, eggplants, peppers, celery—and all the other vegetable crops that fill produce aisles—could find himself subject to regulations as complex as the LGMA for *each* of these crops. Because on-farm food safety regulation affects the entire farm, each one of these crop regulations would in turn affect the entire farm.



Product testing provides another example of the increased costs borne by growers of diverse, multi-harvest crops. The multiple harvests of small plots and many crops on smaller, diverse farms will increase the costs of product testing immensely, compared to fewer harvests of large blocks on big farms.

5. Marketing Act programs and other approaches currently in vogue put farmers in conflict with environmental laws.

Farm food-safety is a single-issue approach in a Marketing Act program. The rules are written with little consideration of, or concern for other practical or environmental considerations. Farm food-safety metrics or GAPs have been associated with habitat removal and destruction in order to control any wild animal, amphibian, bird, rodent, or insect that is considered to be a potential disease carrier. **The same practices that federal and state environmental and farm agencies encourage in order to meet environmental standards, are opposed by Marketing Act food safety programs precisely because they increase natural habitat.** This leaves farmers exposed to liability for violating environmental laws and regulations.

6. Marketing Act Agreements require growers to follow regulations for which the enforcement agencies take no responsibility and accept no liability.

In a remarkable interview with CAFF staff and Board members, the Chief Counsel of the Executive Branch of the California Department of Food and Agriculture (CDFA) described how the Department supported a voluntary program such as the LGMA (an Agreement rather than an Order) because it shielded the Department from food safety and environmental liability.⁷⁹ If the Agreement became mandatory, the Department might become liable for environmental damages.

Neither does the LGMA Board that was appointed by CDFA take responsibility for the on-farm regulations, because it only has legal authority to *enforce* the Agreement. The position of the LGMA Board is that the GAPs were developed by the “industry,” the board simply enforces those rules.

The industry authors of the GAPs, in turn, disclaim liability for any use of the GAPs and have frequently changed them without any public process or rulemaking procedures, except acceptance by the LGMA Board of Directors. The October 16, 2007 version is the third since the LGMA was formally established.

The USDA’s Agricultural Marketing Service claims that a Federal Marketing Act program would follow federal rulemaking. But the same evasions as used in California could also be used at the Federal level, with the same rationale.

7. Marketing Act programs and other current approaches do not address important issues beyond the farmers’ control.

Farms are only one of the three parts to fresh-cut processing safety: before processing; during processing; and after processing. Farms are also only one part of the three parts to whole fresh produce safety: a contaminated farm environment, particularly the contamination of water source; how contamination occurs on farm; and how

⁷⁹ Interview with John Dyer, Chief Counsel, CDFA, Sacramento, 22 Aug. 2007.

contamination occurs in handling. Current food safety approaches give no attention to any of the important issues that are out of the farmer's control.

8. Using Marketing Acts for food safety is beyond the original purview of the Marketing Acts and is probably illegal.

The Federal and parallel State Marketing Acts were a response to the Great Depression and the collapse of commodity prices. They were intended to limit the quantity of production and to create orderly marketing of allowed quantities of crops to achieve target prices. Most uses in the last few decades have centered on using the Marketing Acts for marketing and promotion.

All of these historical Marketing Act controls begin at the "farm gate." None of them implicitly or explicitly concern the control of how farmers actually grow their crops. Using the Acts for on-farm food safety must have been recognized as a legal quandary, even by advocates.

If there were no legal quandary there would have been no need for Title VIII Miscellaneous Provisions, of the proposed Eat Healthy America Act (Cardoza), Section 808, which tries to amend the 1937 Federal Agricultural Agreement Marketing Act to add on-farm food safety powers for specialty crops Agreements and Orders. Nor would there have been need for a similar amendment that Senator Feinstein proposed to the Farm Bill in the Senate.

The California LGMA exists in a legal grey area at best; no one has challenged it because it was the one industry-wide response to the 2006 spinach outbreak crisis, and the first concerted response to the entire history of leafy green outbreaks from California.

9. Over the long term, using the Marketing Acts for farm food safety will diminish consumer choice as well as farmers' freedom.

Establishment, control, and regulatory bias of marketing orders and agreements are all in favor of the largest producers and processors, often functioning as part of a concentrated, industrial-scale production system. The food safety issues of a "crop" become translated into the food safety issues of the largest industrial actors.

Variation in growing practices within a crop and growing a variety of crops are often associated with smaller growers. This is recognized in USDA, Small Business Administration, and states' agencies advice to smaller growers to find unique market niches. This includes both crops themselves and how crops are grown.

Subjecting all producers to the regulations seemingly required for industrial production will limit market entry of smaller producers who can least afford compliance. It will also limit the choices of consumers by reducing the types of farms and farm practices they can support.

10. Using the Marketing Acts for farm food-safety can lead to massive regulation without substantially improving food safety.

Both O157:H7 and *Salmonella* are enteric diseases with major reservoirs in cattle or dairy (*Salmonella* also in poultry). Reduction of these reservoirs in domesticated animals or birds is not addressed. There are no means of addressing environmental sources of pathogen contamination, in water, watersheds, or animal production.

The research and development called for in the Marketing Acts tend to be captured by the issues and approaches of the largest commercial interests. This can lead to the worst of all possible worlds: massive, ineffective regulation that increases industry concentration into fewer and fewer hands.

There have been at least three leafy green disease outbreaks since September 2006, when the metrics and GAPS started being enforced and the date when this document was published: Taco Bell, Taco John, and Dole Hearts Delight.

11. Using Marketing Act programs for food safety exercises national or state control over an inherently local industry, primarily benefiting the largest agricultural entities.

Marketing Act programs create centralized national bureaucratic control over the local and specific conditions of farms, when knowledge of local and specific conditions is what makes farming successful.

The CDC and the FDA had to change their entire outlook on food-borne diseases in the mid-1990s. Outbreaks had become dispersed and multi-state, instead of focused and local. They realized they had to deal with emerging diseases in the context of an increasingly concentrated and centralized food industry. The degree of concentration put large populations at risk from errors in a single processing location exacerbating the paradox of increasing food-borne diseases in a developed country. The fragility of this system is recognized in the Federal Bio-terrorism Act of 2002.

The 2–5% of farms that are part of the concentrated national fresh-cut industry might need federal regulation. Most farmers, who are part of more local systems, do not.

In summary, the LGMA was the only industry-wide approach in California, when one was desperately needed. Legal or not, using the Agreement structure allowed for a faster and more flexible response than other approaches. Clearly, these are advantages, but given the problems and limitations of the LGMA structure, we believe that other frameworks for produce safety regulation should be explored.

VII. E. coli O157:H7 in Beef

The beef industry was looked to for guidance by the fresh-cut produce industry after the 2006 spinach recall. All beef is processed in USDA continuously inspected facilities under mandatory HACCP plans, which include routine microbial testing of product.

Until 2007 there had been a steady decline in O157:H7 beef recalls over the years, while fresh-cut produce recalls, for the same pathogen, were rising. The Food Safety and Inspection Service (FSIS) of the USDA issued a “Timeline of Events Related to *E. coli* O157:H7” which covers from 1993, the major Jack in the Box outbreak, to 2005.⁸⁰ The timeline shows reduction in illnesses and recalls due to beef over a ten year period.

The timeline ends with the 2005 approval of BAX, a microbial testing screening method for O157:H7 that reduces the number of false positives. Beef looked like a good initial guide for leafy green safety regulation. Processed fresh produce lacks the “kill step” equivalent to the correct cooking of beef to eliminate pathogens, but the beef industry cannot count on consumers or food service using adequate cooking time and temperature to constitute a “kill step.” Beef industry safety procedures seemed like a good model for fresh-cut.

2007 was a bad year for O157:H7 in beef

The first big beef disease outbreak in 2007 was the Topps beef recall, eventually covering over 21 million pounds, one of the largest beef recalls in U.S. history. The Topps (New Jersey) investigation and recall extended over nearly a month, starting with an illness investigation confirmed by the FSIS on September 7, 2007.⁸¹ The beef recall was due to *E. coli* O157:H7, the detection method was human consumer illness, and the USDA, which has responsibility for meat safety, was having trouble explaining the 18-day delay in issuing a recall.

The Centers for Disease Control (CDC) issued an updated *Multistate Outbreak of E. coli* O157 Infections Linked to Topps Brand Ground Beef Patties on October 5, 2007. As of October 5, there were 32 cases that matched patients’ strains of O157:H7 to the strains found in Topps beef, a known 65% hospitalization rate, and one case advanced to hemolytic-uremic syndrome (HUS). *Topps announced it was going out of business after the recall was expanded to cover 21 million pounds of frozen beef patties.*

The Topps outbreak and recall was only one of many in 2007 that challenged the status of beef safety. In all, over 29,248,167 pounds of meat were recalled in 2007, in 20 recalls. Well over 100 people were sickened, some developing acute kidney failure.⁸²

HACCP procedures and routine microbial testing are presumed to routinely prevent contamination or prevent contaminated beef from leaving processing plants before recalls

⁸⁰ USDA, 2007.

⁸¹ Hedges, 2007.

⁸² E. coli O157, 2007.

are required. Statistics on the results of routine microbiological tests inside the plant are not generally reported, so the general level of contamination before test-and-hold is not available.

Some of the recalls were identified at the plants, whether by federal or private testing, and were recalled after having left the plants. This indicates that the industry is not testing and then holding before shipment. It is also not clear why major recalls were only initiated after consumer illness investigations or why HACCP and routine microbiological testing failed to stop or identify the major recalls in 2007 after years of reductions in both illnesses and recalls. FSIS is intensifying its regulation of beef after the Topps recall.

Comparison of the beef and fresh-cut leafy green industries

The beef industry underwent major restructuring years in advance of the fresh-cut leafy green industry, with some parallels. Changes in beef production resulted from concentration of cattle into ever larger feedlots before slaughter and from a longer running trend of changing cattle nutrition from grazing on pastures to increasing reliance on corn and supplement-based feeds. These changes in feeding practices have been shown in some research to encourage O157:H7 in cattle.⁸³

Both beef and fresh-cut leafy greens have the major food safety issue of O157:H7. The apparent breakdown of beef food safety procedures directed at O157:H7 in 2007 is a warning to the fresh-cut leafy green industry, which looked to beef safety as a model.

The warning can be taken as technical: current food safety practices need to be reexamined. But the warning has deeper significance as a challenge to all the new regulations proposed for produce when a well-established industry like meat packing, regulated for almost 100 years, fails to achieve food safety after 14 years of increased regulation (albeit without ever attacking the source.) This is a failure in the face of implemented HACCP, microbial testing and governmental controls, such as plant inspectors, at a level the leafy green fresh-cut industry does not even aspire to. These controls seem important: they reduce food safety incidents. But, they are apparently inadequate.

Beef food-safety regulations focus on the processing plant, while fresh-cut food-safety regulations focus on the farms, before processing. The two industries take, in a way, opposite regulatory approaches: beef safety is regulated almost exclusively in the processing plant, while fresh-cut safety metrics (currently) exclude the processing plant.

Both beef and fresh-cut leafy greens might benefit from a four-part approach. Three of the parts were presented for fresh-cut, and could also apply to beef. Pathogens must be controlled: (1) before the processing plant; (2) in the processing plant; and (3) after the processing plant. **It is critical for both industries to add a fourth component. (4) Vegetable growers, ranchers, and public agencies must cooperate in an effort to**

⁸³ Jacob, 2008.

reduce the level of this pathogen in the general environment *before* farms and water become contaminated.

The beef and dairy industries are in a crucial position to deal with pathogens in the general environment contaminating farms. Cattle are a major reservoir of human enteric pathogens including O157:H7 and *Salmonella*. Cattle are the primary reservoir of O157:H7. Pathogens flow on an almost continuous basis from the concentrated reservoirs in cattle feedlots and mega-dairies through waste disposal into farm environments. Contamination pathways can be *direct* (mainly through manure from cattle, but also dust, flies or other vectors of transmission from dairies) or *indirect* (from contaminated water sources or potentially, wildlife that drinks contaminated water or is exposed to feces.)

Cycling of E. coli O157:H7 in the environment

The *E. coli* pathogen cycle is analogous to the nutrient cycles discussed in biology and agriculture: the nitrogen cycle, the phosphorous cycle, the carbon cycle. Enteric pathogen cycles differ from nutrient cycles mainly because pathogens can increase at every stage, and in particular in cattle and cows. Persistence and increase in pathogens can occur at many points, including on plant surfaces.⁸⁴

Understanding and controlling the pathogen cycle should be a major goal of farm food-safety research. However, reducing or eliminating enteric pathogens, particularly O157:H7, in the primary reservoir of beef cattle, or flowing from the primary reservoir, would stop the continuous inoculation of pathogens into the farm environment. It would be a good, known place to start.

Manure-based composts produced under the National Organic Program of the USDA are one of the only farm inputs required to have human pathogen safety. When the federal law was written, the process for ensuring the safety of compost containing animal manure was based on EPA-approved methods for composting human waste as a farm fertilizer. At the time this was thought to be using an over-abundance of caution. Organic composts, produced according to the Act, can kill both O157:H7 bacteria and Stx-gene phages, though they still should be tested. In ongoing research the margin of safety looks adequate, but not by much.

The transmission and persistence of O157:H7 in feedlots despite massive population turnovers remains complex. O157:H7 incidence follows a temporal sequence, where it has been studied in particular feedlots. The susceptibility of cattle varies with age, and a relatively small percentage of cattle have been found to be responsible for the majority of pathogens shed at one time. For example, researchers found that targeting just 5% of the most infectious individuals, by itself, could significantly decrease transmission of O157:H7 within herds, in some cases by over 90%.⁸⁵

⁸⁴ Aruscavage, 2006.

⁸⁵ Mathews, 2006.

There has never been an attempt to systematically reduce and restrict O157:H7 at its source in cattle and dairy. No public agency currently has the mission, responsibility or power to look at systematic source reduction as a public health issue that would affect two major animal industries, their suppliers, including hay and feed suppliers, and their waste disposal as manures onto farms. In California there have been no systematic surveys of O157:H7 prevalence in cattle and dairies,⁸⁶ the emphasis is on nutrient recycling, and avoiding nutrient contamination of water or aquifers from feedlots and mega-dairies as the major waste disposal problem.

It is not clear how substantial the changes would have to be in the cattle industry or in feedlots to greatly reduce O157:H7. One approach is being tried in Canada where the first commercial cattle herd has been vaccinated against O157:H7 under an experimental permit. A very different approach would be to look at the practices of "pure" grass or range fed cattle operations and see if they reduce or eliminate O157:H7 as an issue, and if so, why and how this happens.

The beef industry could benefit from having less of a pathogen risk entering the slaughterhouse, which gives their processing controls a better chance to succeed. It also would benefit from fewer contaminated animals coming from ranch to feedlot. Increased shedding of O157:H7 following stress or lack of food and water makes transportation to feedlot a critical control point.

California's role in U.S. fresh fruit and vegetable safety may be unique in four ways. It is the major producing state for many fruits and vegetables and for leafy greens going to fresh-cut in particular. It is characterized by very large, "industrial" concentrated feedlots and dairies with the tremendous waste disposal problems these create, including the export of manures and other byproducts. California agriculture is subject to high development pressure from housing, from commercial and industrial use, and from the disposal of municipal and other wastes from urban areas. Finally, the Salinas Valley and Central Coast watersheds are key vegetable producing regions, intermixed with local ranching, key environmental coastal areas, and high urban pressure including competition for water resources.

Major transport of high-risk inputs such as feedlot manure wastes, into farming regions, should consider enteric pathogen safety standards. Local ranchers need to be included in watershed management designed to prevent contamination of aboveground rivers and streams, shallow wells, and deeper aquifers. Solving the problems of enteric pathogen cycling in California for concentrated cattle and dairy industries and for a concentrated fresh-cut industry would be a major benefit for national food safety. Currently it seems doubtful that the disparate commercial, legal, insurance and liability, research and political agendas can align to solve what appear to be common problems. Instead there appears to have been a focus on the political and economic struggle for control of the process of crisis management, at the expense of farmers, the environment, and public health.

⁸⁶ Western Institute for Food Safety and Security, personal communication with author.

Shift-workers in beef and fresh-cut: labor, farm workers, and employees

Human beings are part of the pathogen cycle also. They contribute through human wastewater recycling plants that supply irrigation water, as in the Salinas Valley. More directly, ill workers have the potential to contaminate product in the field, handling or in processing. Farm workers and shift workers should be seen as active participants in food safety, but sometimes they are focused on in investigations as potential disease carriers only. How management understands the impact of farm laborers has a critical impact on food safety.

For example, in the new farm investigation manuals, put out by the US Department of Health and Human Services for FDA investigations of produce-borne food outbreaks, the main issues are: were workers ill, what were they ill with, and how is it documented? Investigators are not directed to interview line employees and ask for their observations regarding food safety issues.

For most conventional food processors the author has worked with, a stable, experienced, workforce that is intimately familiar with food safety issues is crucial. When temporary labor is used it has to be in a context where shift-leaders or experienced employees can work with and communicate with them to insure food safety on the processing line. Their entire business, as well as their customer ethics, requires it.

Management's attitude towards labor, including line managers, has the potential to enhance or destroy food safety. When union officials testified before the California Joint Assembly and Senate Agriculture hearing on leafy green safety in February 2007, they asked to be included in food safety discussions. The 2006 spinach crisis had put a lot of employees out of work, both in processing plants and on farms. They were motivated about food safety as an issue and discussed practices their members had reported that could compromise safety. One memorable example was that processing employees were rushed in taking sanitation breaks. There was not enough time to first take off, and afterwards, put back on their food safety gloves.⁸⁷

Another example comes from the original O157:H7 beef outbreak at Jack-in-the-Box. Bill Marler, the *E. coli* attorney, described a key moment in the discovery process for the lawsuits against Jack-in-the-Box (again from his Salinas talk). They found an e-mail to a shift-worker. She made the suggestion that the hamburgers should be cooked longer. Using the new standard operating procedures, which workers had to follow, the hamburgers were coming out too raw and she was getting negative customer reactions.⁸⁸ However, standard operating procedures were not changed. Sometimes management and regulators have to listen to the observations of line employees, to shift-workers or contract farm laborers, if they want to have food safety.

⁸⁷ Cohen interviews.

⁸⁸ Bill Marler, attorney, speaking at Steinbeck Center, Salinas California, 28 Feb. 2007.

VIII. A Different Approach to Farm Food Safety

1. Reduce human pathogens throughout the pathogen cycle in the farm environment.

A critical component is currently missing from the efforts to prevent *E. coli* contamination of food. The agencies and industries involved in the food safety effort (HHS and FDA) *should have the mission of reducing or eliminating human pathogens throughout the pathogen cycle in the environment.* A lead agency should have the mission of cutting off the flow of O157:H7 from the primary reservoirs in feedlots and large dairies to the rest of the environment. That includes setting standards for enteric pathogen levels in all farm inputs that go into cattle and dairy, and all farm “exports” from dairy and cattle (like manure) that enter the rest of the agro-ecosystem. This effort should also include environmental practices designed to reduce flow of contaminated water onto crop farming areas.

2. Develop and enforce specific food safety regulations for all phases of the fresh-cut industry, including processing plants.

CAFF recommends developing specific food safety regulations for all phases of the fresh-cut industry, including processing plants. The approach starts with identifying fresh-cut as a separate, unique, processing industry with special on-farm food safety requirements. Regulations designed for growers who grow for fresh-cut should only apply to those growers, including foreign growers. This might apply to fewer than 1,000 farmers in the entire U.S. Further, farmers who choose to produce for fresh-cut will have to accept fresh-cut regulations for their entire farm through this voluntary contractual relationship. Food safety for the farmers who do not choose to produce for fresh-cut is a separate issue, with its own requirements depending on risk, farm size, and history.

3. Encourage environmental stewardship as an integral part of food safety.

Farm food safety regulations should not conflict with other laws and regulations that farms are subject to for environmental protection, including Endangered Species Act, Clean Water Act, Air Quality regulation and others. **Good Agricultural Practices have to mesh with Best Management Practices.**

4. Provide educational materials on food safety to limited-resource growers and provide all farmers with the tools they need to address food safety on their farms.

Education regarding food safety metrics should be made available to farmers growing for the traditional whole fresh market. These farmers have not caused multi-state outbreaks. Since a disease outbreak is defined as “two or more cases” caused by a reportable pathogen, they do not appear to have caused local disease outbreaks either.

There are great social costs from regulating all growers as if they were industrial growers. Loss of diversity in all aspects of farm production is too high a social cost. Regulation that is ineffective at solving food-safety issues, but efficient at driving growers out of farming is too high a social cost.

5. Identify and track serious human pathogens in watersheds.

Pathogen contamination of the environment surrounding farms cannot be solved on a farm-by-farm basis and should not be considered solely a produce grower responsibility. Farmers should have the right to safe irrigation water. Drinking water is supposed to be safe for drinking. Farm water should be safe for farming. This may involve careful analysis and evaluation of the farm environment watershed by watershed. The local community watershed groups that are active in many agricultural regions of the state are well-placed to take a lead role in this.

To protect public health, the government ought to identify and track serious human pathogen risks in the farm environment, to inform water districts and farmers, and to help with the costs and technology of cleaning up the sources of the pathogens

6. Support partnerships between ranchers and dairymen, researchers, watershed or water quality experts, and cooperative extension specialists to address food safety issues.

These partnerships must be developed to explore practical best management practices that reduce problems with pathogens while enhancing animal husbandry and environmental stewardship. Financial incentives and support for these partnerships will be necessary.

7. Conduct research into reducing the human disease impact of O157:H7.

The human-health impacts of O157:H7 warrant further research. Because the number of U.S. patients affected by O157:H7 is so low from a pharmaceutical perspective, very little research is done and potential new therapies are regulated under the Orphan Drug Act. However, the public's perception of the threat can shut down the marketing of an entire crop, or cause consumer loss of confidence in fresh fruits and vegetables.

If O157:H7 caused less damage because there were therapies available for treatment of the worst symptoms, then the food-safety risks for farmers, processors, and consumers would all be greatly reduced.

8. Conduct research into food safety that is practical for all sizes and types of farms, ranches and dairies.

Research should be oriented towards solving pathogen safety issues for all sizes and types of farms, ranches, and dairies. Practically oriented studies should be conducted into: understanding the cycling of the pathogen through soils and rangelands; understanding relationships between these pathogens and the use of antibiotics in animal production; protecting the microbial safety of all farm inputs; and animal husbandry practices that reduce the incidence and shedding of O157:H7.

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