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Making Salad Safe Again:
The Network Structure of Food Safety Regulation

Everyone in the leafy greens industry remembers where they were on Friday, September 15, 2006—the day that news headlines announced an FDA warning to consumers not to eat bagged spinach. Drew McDonald, who managed food safety at Taylor Farms, a leading producer of fresh-cut fruits and vegetables, was at the baggage claim of an airport in Hawaii, where he, his wife, and baby girl had arrived for weeklong vacation. When he turned on his phone to activate an out-of-the-office voicemail notification, he discovered dozens of messages from company customers and members of his team concerned about a major foodborne illness outbreak. “As I was listening to the messages,” he recalls, “I looked up at the TV monitors, and there, scrolling across the bottom of a CNN news broadcast, was ‘spinach outbreak…people sick…’ So I started calling around to find out what was going on.” The FDA was blaming bagged spinach for an emerging nationwide outbreak of *E. coli* O157:H7 responsible for fifty reported cases of illness, including eight involving kidney failure and one death. Later in the day, the FDA expanded the warning to cover all fresh spinach. Agency officials had learned that bagged spinach was sometimes sold out of the package in salad bars and retail stores, and the number of reported cases had risen to ninety-four, with fourteen victims now suffering kidney failure. McDonald monitored the situation by phone for a day-and-a-half “as the industry descended into mayhem.” Aborting his vacation, he and his family boarded a plane back to California on Sunday. They were upgraded to first class and, as they settled into their seats, the stewardess apologized that she would not be serving the lunch appetizer listed on the menu: spinach salad.

“When FDA said ‘Don’t eat spinach,’ it pretty much shut down the bagged leafy greens industry,” recalls David Gombas, a microbiologist who directs food safety efforts at the United Fresh Produce
Association, a leading trade group. Frightened consumers stopped eating not only spinach but all bagged produce. Consequently, leafy greens production halted for two weeks at the height of the California growing season. “You had an entire crop of spinach that was past due sitting in the ground, so companies were losing hundreds of thousands of dollars a day because everything was essentially on hold,” explains McDonald. Workers and farmers also suffered significant losses. “We had a lot of families who really came upon hard times because there was no work for people,” remembers Bob Whitaker, Chief Science and Technology officer at the Produce Marketing Association, who worked at the time for NewStar Fresh Foods, a leading grower and shipper of fresh produce in California’s Salinas Valley. “Each day I would show up at the plant to tell my hourly workers—who needed to work fifty or sixty hours a week to make ends meet—that we had no work today. The farmers who were growing our product had already sunk money into the ground and planted the seeds, but we couldn’t harvest it. We had no place to put it.”

Robert Brackett, then director of the FDA’s Center for Food Safety and Applied Nutrition, recalls that the agency’s warning to avoid bagged spinach, expanded to include all fresh spinach, was “unprecedented.” Typically, when the agency learned of an outbreak, it would ask the responsible company to issue a public announcement and initiate a recall of the contaminated product. In rare instances when companies refused, the agency would issue its own targeted warning limited to the brand in question. However, a special sense of urgency led FDA officials to issue a broad warning regarding all fresh spinach before identifying a specific company responsible for the contamination. With dozens of reports of E. coli O157:H7 infections arriving simultaneously from around the country, FDA officials “were concerned about fresh spinach products that could still be in consumers’ refrigerators,” explains Brackett. “At that point, the priority was to prevent further illnesses. We wanted to get the word out and get fresh spinach off the shelves while we conducted an investigation to narrow down the source.”

Moreover, in the shadow of 9/11, officials feared that the outbreak might be a case of bioterrorism. However, as the investigation progressed, fears of intentional misconduct abated, and agency officials narrowed down the possible source of the contaminated spinach to three counties in central California. Within two weeks of its first warning, the FDA announced that it had traced all spinach implicated in the
outbreak to a single processing plant operated by Natural Selection Foods, a company that bagged spinach for a number of leading brands, and the agency limited its warning to those specific brands. But by then, it was too late for the industry.  

Every leafy green grower and packer suffered fallout from the FDA’s broad warning not to eat spinach. “Our products were not part of this at all,” recalls Whitaker. “We were not growing in the areas that had a problem, but nobody wanted our products.” Ironically, “the only company that got insurance reimbursement was the company that sold the contaminated product, because the rest of us hadn’t done anything that would trigger insurance coverage.” Before the FDA warning, says Gombas, “bagged leafy greens were a double-digit growth product. Each year sales were increasing like crazy. That just stopped.” According to Whitaker, “The industry really didn’t get started again until it made its seasonal move down to Arizona in November. And even then, it started up very slowly. It was five, six, seven years before the volume of sales came back to where it was in 2006. Some will tell you it never came back.”

According to one estimate, California leafy greens producers suffered nearly $100 million in losses following the outbreak. “[D]espite the actual narrow cause of the outbreak, the entire fresh spinach industry has suffered a tremendous blow,” Whitaker testified at Senate hearings in November. “Growers and processors of fresh spinach that had perfectly safe product in the marketplace, including my company, pulled our product from retail shelves, warehouses, processing plants, and even stopped harvesting.” Whitaker called on Congress to compensate companies adversely affected by the FDA’s warnings but not implicated in the outbreak.  

The FDA was unapologetic about its aggressive response to the outbreak. In the same public announcement that limited its warning to spinach bagged by Natural Selection Foods, the agency chided the entire industry for a “long history of *E. coli* O157:H7 outbreaks involving leafy greens from the central California region” and stated that federal and state authorities “expect the industry to develop a comprehensive plan which is designed to minimize the risk of another outbreak.” This was not the first time that that the agency had expressed its concerns about food safety to California’s leafy greens growers. In February 2004, the agency had sent a letter to growers, packers, and shippers of lettuce and
fresh tomatoes prompted by more than a dozen outbreaks since 1996 involving contamination of these products with *E. coli* O157:H7, *Salmonella*, *Cyclospora*, and Hepatitis A virus, which caused 859 reported cases of illness. The letter urged companies “from the farm level through the distribution level” to “review their current operations” and to take “appropriate measures to provide safe product to the consumer.” Then again, in November 2005, the agency had issued a warning letter specifically addressed to California’s leafy greens growers, packers, processors, and shippers reiterating its concerns. The letter cited eighteen *E. coli* O157:H7 outbreaks since 1995 traced back to lettuce and one to fresh spinach, which were responsible for 409 reported cases of illness and two deaths.7

Industry members protested that existing FDA food safety guidance lacked specificity and that the agency’s outbreak investigations had routinely failed to definitively identify the sources of contamination. FDA officials responded that the industry had ignored research findings from the California Department of Health Services (CDHS) dating back three years documenting contamination of agricultural water by sewage and animal waste. The agency insisted that the industry’s “claims that ‘we cannot take action until we know the cause’ are unacceptable.”8

The magnitude of the September 2006 spinach outbreak far surpassed previous leafy green outbreaks. Public health officials eventually attributed over 200 reported illnesses in twenty-six states to the outbreak. One hundred and three victims required hospitalization, thirty-one suffered kidney failure, and three died.9

Investigators never conclusively identified the precise cause of the contamination. Thirteen bags of Dole baby spinach, packed by Natural Selection and recovered from victims, tested positive for the outbreak strain of *E. coli* O157:H7. Eleven of the bags were stamped with the same lot number, and investigators traced the spinach in that lot to four fields. A mile from one of the fields, they found the outbreak strain of *E. coli* O157:H7 in samples that they collected from cattle feces, wild pig feces, and river water. Paicines Ranch, a grass-fed beef operation, owned the field and leased it for crop production. None of the samples collected from the field itself or within a mile of the field tested positive for *E. coli* O157:H7. Investigators speculated that the contamination could have been caused by the incursion of
wild pigs into the spinach rows or the infiltration of contaminated river water into irrigation wells. They also noted that samples taken from the areas surrounding the other three fields in question yielded non-outbreak strains of *E. coli* O157:H7 which, along with the results of previous outbreak investigations, indicated “systematic contamination” of waterways throughout the Salinas Valley.\(^{10}\)

In the years preceding the 2006 spinach outbreak, food safety had become a growing concern within the leafy greens industry although, according to Gombas, it was not yet a top priority. He recalls that, in 2005, when he started working in the fresh produce sector as a microbiology expert at United Fresh, “food safety was a minor part of what the industry was looking at. Most of the questions I received from industry members at the time were about shelf life, varieties, packing—issues related to product quality. I remember a meeting with CDC officials who said that, of the last 130 foodborne illness outbreaks, thirty-five percent were linked to fresh produce. Around this time, things were starting to shift; food safety was really becoming visible in the fresh produce world.”\(^{11}\)

Companies that instituted more rigorous food safety programs were frustrated when foodborne illnesses were traced back to their products despite their efforts. As an example, Gombas cites Dole, which, after a number of outbreaks traced back to the company’s lettuce, “had a good food safety team in place. They were doing everything they could think of to preserve the safety of the leafy greens they were growing. They were trying their best. And yet, the outbreaks were occurring anyway. Everybody at the time was struggling to figure out ‘What’s going on? How do we stop it?’” The 2006 outbreak spread the pain, explains Gombas. “It was devastating to the industry, and it served as a real wakeup call, a watershed event for food safety in fresh produce.”\(^{12}\)

In response, experts in the fresh produce industry designed and launched a program that relies on government inspectors to verify compliance with industry standards aimed at reducing the risk of microbiological contamination in growing fields. At the same time, leading retail stores, restaurants, and food service companies increased the stringency of food safety requirements in their product specifications and required their fresh produce suppliers to obtain certification of compliance from a private third-party auditor. Outbreak victims filed lawsuits against growers, processors, and retailers,
which created an additional source of pressure to improve food safety practices. The 2006 spinach outbreak also boosted efforts of consumer advocates pushing for new government regulations, which Congress finally authorized in the Food Safety Modernization Act of 2010.

Surprisingly, no one knows whether any of these efforts has reduced the risk of foodborne illness. Many experts suspect that they have, but quantitative data suggest merely that more stringent standards and more frequent inspections have increased farmers’ adoption of recommended best practices, without demonstrating that all of the added expense has improved public health. When asked whether decades of investing company and government funds into food safety in the fresh produce sector has paid off, food safety managers and government regulators admit that they are motivated by a largely unsubstantiated faith that their efforts are making salad safer. As one leading expert put it, “There’s a sense that the industry has really raised the bar, in part because we do see fewer of these outbreaks and fewer of these illnesses. I just have a hard time pointing to any specific numbers.” A widely circulated report praising food safety reforms in the leafy greens industry following the 2006 baby spinach outbreak conceded that a distinguished panel of experts “struggled with finding supportive data to prove their general positive sense of a decreased risk.”

In addition to exposing a lack of reliable quantitative data linking food safety reforms to health outcomes, this chapter provides a thick description of interconnections between different efforts following the 2006 baby spinach outbreak to reveal that food safety regulation has a network structure. Within this network structure, collaboration between industry and government blurs the traditional distinction between private ordering and public law. The network structure of food safety regulation also makes it difficult to trace the origin of standards back to authoritative rulemaking bodies. Instead, standards appear to emerge out of interactions among individuals and institutions throughout the network, and they evolve gradually over time through feedback and learning.
Fresh produce presents a number of unique food safety challenges. “Fresh produce is grown out in the field. It’s grown under the sky. It’s grown in the dirt. It’s grown in the presence of animals,” explains David Gombas. “It’s exposed to all sorts of risks, and really there’s nothing in the farming process that will prevent those risks from coming in contact with the produce. So you can’t eliminate the risks; the best you can do is control them.” Risk management in the field is especially important because fresh produce is frequently consumed raw, which forecloses the use of cooking to kill harmful pathogens during processing or home preparation. Washing fresh produce with chlorinated water reduces pathogen levels but is not 100% effective. Indeed, if not properly monitored, wash water can be a vehicle for cross contamination. Irradiation also reduces pathogen levels. However, it has not been widely adopted because the necessary equipment is expensive and companies fear that many consumers will not purchase irradiated food.14

Leafy greens that have been cut and processed carry additional risks. Cutting breaks the protective exterior skin of the plant and allows pathogens to infiltrate the leaves where they are harder to remove. Cutting also releases cellular fluids that provide a nutritive medium that can foster pathogen growth. The cutting, washing, and mixing of packaged salad greens exposes them to additional handling, thereby multiplying opportunities for contamination. The aggregation of greens from different sources during processing increases the risk of cross contamination and can disperse a single contaminated spinach plant or head of lettuce into multiple finished products.15

Food safety concerns about fresh produce are relatively recent compared to other sectors, such as dairy and meat. “Up until the 1990s, nobody ever thought about fresh produce as being a risk,” explains Gombas. A 1985 National Academies report observed that “[r]aw fruits and vegetables are not common causes of foodborne illness in the United States.” Although the FDA had broad legal authority under the Federal Food, Drug and Cosmetic Act to prevent adulteration of any type of food sold in interstate commerce, it had never developed implementing regulations for fresh produce as it had for processed
foods. The agency’s Good Manufacturing Practices (GMPs) governing food processors expressly excluded “[e]stablishments engaged solely in the harvesting, storage, or distribution of one or more ‘raw agricultural commodities’”—i.e. farms and produce packing operations.  

Neither federal nor state authorities inspected farms or packing operations except when investigating outbreaks. Fresh produce “was under the radar for most federal and state officials,” recalls Whitaker. “During the first four or five years I was in the industry in the late 1990s, I was never visited by an FDA or State of California official. I never saw them.” According to Michelle Smith, a longtime FDA official, “we didn’t tend to go on farms unless we had a reason to be there.”

Outbreaks associated with fresh produce starting in the mid-1990s raised new food safety concerns. Increased consumption of raw produce as part of changing dietary patterns that favored fresh salads over cooked vegetables likely contributed to a rise in outbreaks. In addition, growing demand for the convenience of pre-cut, ready-to-eat (known as “fresh-cut”) produce in packages bearing brand names made it easier for public health officials to trace outbreaks caused by bagged salad mixes back to particular companies. Improvements in foodborne illness surveillance and tracing further enhanced the ability of public health officials to connect outbreaks to particular products and companies, both in the growing fresh-cut sector as well as traditional unmarked produce sold in bulk.

In response to growing concern about the safety of fresh produce, experts in industry, government, and academia began to formulate what became known as Good Agricultural Practices, commonly referred to as GAPs, aimed at reducing the risk of microbial contamination during growing and harvesting. The term GAPs is sometimes used to include Good Handling Practices (GHPs) for post-harvest sorting, packing, storage, and shipping. The International Fresh-Cut Produce Association and the Western Growers Association organized a Food Safety Initiative to coordinate these efforts. They assembled a Steering Committee consisting of representatives from five trade associations, six grower-processors, two cooling companies, a shipper, a private food safety laboratory, and a county agricultural commissioner. They also assembled a nineteen-member Scientific Task Force composed mostly of academics and industry experts with PhDs in food science, crop science, microbiology, virology, and toxicology. Also
engaged in the effort were government officials from the FDA, USDA, California and Arizona
departments of agriculture, and the California department of health.\(^19\)

In the summer of 1997, the International Fresh-Cut Produce Association and the Western Growers
Association published a thirty-five-page booklet, *Voluntary Food Safety Guidelines for Fresh Produce.*
Reflecting the limits of science regarding pathogen control on farms, the booklet dedicates only three
pages to the risk of contamination in fields from soil, fertilizers, irrigation water, animal intrusion,
workers, and harvesting equipment. The remainder deals with risk management in precooling facilities,
transportation, packinghouses, and processing plants. That same year, the United Fresh Fruit and
Vegetable Association published a similar twenty-eight-page booklet, *Industrywide Guidance to Minimize
Microbiological Food Safety Risks,* and academics at Cornell University published a tri-fold pamphlet,
*Prevention of Foodborne Illness Begins on the Farm.*\(^20\)

By and large, these early GAPs merely direct attention to potential problems without providing
specific procedures or metrics for reducing risk. For example, with regard to soil, the *Voluntary Food
Safety Guidelines for Fresh Produce* state that “Growers are encouraged to research and review the
previous uses of the fields as well as adjoining fields. Suggested questions to be asked, answered and
reviewed include: Do animals have access to the field? What was the last crop grown? What was grown
in the adjoining fields? Was the field ever used as a feedlot, land fill, or toxic waste site?” The guidelines
then recommend that “If the previous use is unknown or if any of the questions lead the grower to believe
a potential hazard exists, it is suggested that soils be tested for contaminants. If the concern is confirmed,
implementing corrective action prior to planting a crop is encouraged.” With regard to fertilizers, the
guidelines suggest that “fertilizers such as manure and compost should be monitored for possible
microbial pathogens,” and they advise growers to “consider a minimum application to harvest interval to
assure that manure or compost has fully broken down in the soil before the crop is harvested.” The
guidelines on irrigation water encourage growers “to identify and review the source of water used on the
ranch” and suggest that “The water may be tested for contaminants on a periodic basis. The frequency of
testing may be determined by the water source. Testing may be considered for *E. coli* and total coliforms.”

In some areas, the guidelines offer slightly more direction: “portable toilets should not be cleaned in the field,” “rubber gloves, leak-proof band aids or other corrective measures are encouraged for minor cuts” on workers’ hands during harvesting, and “[g]rowers are encouraged to clean and sanitize or disinfect tables, baskets and mechanical harvesters on a daily basis.” The guidelines in a few instances refer growers to government regulations. For example, with regard to field sanitation, they state that “[t]he number, condition and positioning of toilets must meet all local, state and federal guidelines.”

The authors of the guidelines lament the lack of science to support more specific instructions to growers, and they openly acknowledge the need for further development. They write in the introduction that “There are data gaps in understanding the sources and significance of microbial hazards as well as practices to minimize them. Consequently, it is not well understood what specific impact water, manure or employees may have in contributing to foodborne disease.” They caution that “The guidelines are not ‘final,’ as they will be revised periodically as experience, new research and new technology may suggest. Additional developments in the fields of microbiology, epidemiology and the evolving understanding of new and emerging disease issues will assist in developing preventative strategies.” The authors advise any “grower, packer, shipper, or processor” who “determines that a potential for risk exists” to “contact either their local trade association, professional consultant, state or local agricultural department official or other government entity to determine what, if any, remedial tasks should be performed to minimize or eliminate the potential risk.” In addition to improving food safety practices within industry, the authors intended the guidelines to reassure “retailers, food service firms, media, advocacy groups, regulatory officials and consumers” of the industry’s “current and evolving attention to these issues.”

In October 1997, President Clinton announced a Food Safety Initiative which promised new federal guidance on good agricultural practices for fresh produce. The FDA and USDA officials charged with developing the new federal GAPs guidance for fresh produce relied heavily on the previous efforts of industry associations and academics. “This is probably a really good example of leveraging the work of
other people,” recalls longtime FDA official Michelle Smith, who played a leading role in developing the guidance. “We quickly found guidance that had been jointly developed by the Western Growers Association and the International Fresh Cut Produce Association, another guidance by United Fresh, and a third guidance put out by Cornell University. And so our first step was to take the best bits of each, weave them together, and present that as our working draft to stakeholder groups.” The draft went through “various rounds of input and modification from industry and academia,” recalls Trevor Suslow, one of the nation’s leading academic experts on food safety in fresh produce, who advised both industry groups and government agencies in the development of GAPs standards. In October 1998, the FDA and USDA published a Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.24

Like its industry and academic predecessors, the federal government’s 1998 guidance highlights areas of concern but provides only slightly more specific instruction to growers. For example, the guidance states that irrigation “[w]ater quality should be adequate for its intended use” and defines “adequate” as “that which is needed to accomplish the intended purpose in keeping with good practice”—a definition likely to leave growers wondering how to assess water quality. The guidance advises that “[w]here water quality is unknown or cannot be controlled, growers should use other good agricultural practices to minimize the risk of contamination,” such as “protecting surface waters, wells, and pump areas from uncontrolled livestock or wildlife access to limit the extent of fecal contamination” and employing “[s]oil and water conservation practices such as grass/sod waterways, diversion beams, runoff control structures, and vegetative buffer areas” to “help prevent polluted runoff water from contaminating agricultural water sources and produce crops.” The guidance offers no details on how to protect water sources from animal intrusion or specifications for earthworks to divert runoff water. Similarly, the guidance states that “[g]rowers may elect to test their water supply for microbial contamination” but, as one commentator points out, does not specify “what to test for, what type of test to utilize, where to test, what the frequency of tests should be or any parameters upon which to evaluate the results of the tests.” For more specific instructions, the guidance suggests that “[g]rowers can consult local water quality experts, such as state or
local Environmental Protection or Public Health agencies, extension agents or land grant universities, for advice appropriate for individual operations.”

Also like its industry and academic predecessors, the federal government’s 1998 guidance highlights the inadequacy of scientific knowledge at the time and the need for additional research. The guidance explains that “the scientific basis for reducing or eliminating pathogens in an agricultural setting is evolving and not yet complete.” For example, the guidance cautions that “there are a number of gaps in the science upon which to base a microbial testing program for agricultural water[,] and microbial testing of agricultural water may be of limited usefulness.” Moreover, like the industry and academic guidelines on which it was based, the government’s guidance is nonbinding. It merely “represents the current thinking” of its authors, and compliance with its suggestions is entirely voluntary.

In contrast to these early GAPs, Good Manufacturing Practices (GMPs), designed to reduce the risk of microbial contamination in post-harvest processing, offered more specific guidance. By 1997, the International Fresh-Cut Produce Association had already published three editions of its leading GMP manual, *Food Safety Guidelines for the Fresh-cut Produce Industry,* originally published in 1992, which provided specific methods and metrics for pathogen testing, detailed equipment and plant design suggestions, step-by-step equipment and facility cleaning procedures, and a model plan to help processors design, implement, and monitor measurable risk reduction routines. During the late 1990s and early 2000s, food processing in other sectors provided expertise and experience that informed the efforts of fresh produce processors to improve their food safety management. For example, Dole drew on experience in its canned fruit and juice divisions in the design and operation of its fresh-cut produce plants. David Gombas, hired by the United Fresh Fruit and Vegetable Association in 2005 brought with him two decades of experience working in the processed food sector implementing risk management.

While the sophistication of GMPs in fresh produce processing developed, the refinement of GAPs lagged behind. Suslow explains that “very few people had the combined expertise in microbiology, agronomy, horticulture, and practical experience dealing with and thinking about the issues related to contamination and sanitation for those types of products at the farm level, or even awareness of the
diversity of sources of irrigation water, the practices related to the use of manure, or the composting process.” A 2001 report on Preventive Control Measures for Fresh & Fresh-Cut Produce by the Institute of Food Technologists, commissioned by the FDA, concluded that “there are no known mitigation strategies that will completely remove pathogens after contamination has occurred while maintaining produce freshness.” This meant that, no matter how much processors improved food safety in their own operations, they remained vulnerable to contamination in the field.28

Continuing outbreaks associated with fresh lettuce and tomatoes led the FDA to issue its warning letter to these two industries in February 2004 urging companies to “review their current operations in light of the agency’s guidance for minimizing microbial food safety hazards.” In October, the FDA published a Produce Safety Action Plan for fresh produce, pledging to “develop, and assist in the development of … commodity-specific and practice-specific guidance.” In its subsequent November 2005 warning letter to the California leafy greens industry, the agency urged industry members “to begin or intensify immediately efforts” to “expedite completion of the industry-led lettuce and leafy green-specific supply chain guidance.” Smith remembers that agency officials saw the warning letters as a way “to push our expectations for more action than we had been seeing up to that point.”29

Hank Giclas, of the Western Growers Association, recalls a series of meetings between industry representatives and FDA officials during this time. In these discussions, the FDA focused on “the fact that there were a few commodities where we were continuing to see outbreaks—tomatoes, cantaloupes, leafy greens, green onions, and culinary herbs—which the agency called ‘high-risk’ crops.” The agency insisted that “there must be something unique about those commodities, because general ag practices, if they were being deployed, weren’t having the effect of reducing the potential for outbreaks…. They said, and we agreed with them: ‘You in industry need to go back and look at what is unique about these crops, and decide if there are additional good ag practices that need to be created and put out there to try to reduce the frequency of these outbreaks.’ And that was the genesis of the industry’s work on commodity-specific guidance.”30
In April 2006, shortly before the Dole baby spinach outbreak, the International Fresh-Cut Produce Association, the Western Growers Association, the United Fresh Fruit and Vegetable Association, and the Produce Marketing Association published *Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain* with input from fifty leading food safety experts from industry, government, and academia. The foreword emphasizes that the guidelines are entirely voluntary and intended to merely “raise awareness” of “potential” food safety issues and to offer general suggestions for addressing them. Consequently, “it is the responsibility of individuals and companies … to determine what actions are appropriate in their individual operations. … This guidance document, as presented, is not sufficient to serve as an action plan for any specific operation but should be viewed as a starting point.”

The industry’s commodity-specific GAPs did little to advance food safety in field operations beyond previous attempts. The new GAPs were “built largely on the 1998 GAPs guidance,” recalls Gombas. For example, with regard to water, the 2006 commodity-specific guidelines paraphrase the 1998 FDA/USDA guidance by suggesting growers assure “that irrigation water and water used in harvest operations is of appropriate microbial quality for its intended use.” The guidelines advise growers to reduce human pathogen contamination of soil without providing any further guidance. They suggest that “[w]ater may be tested on a regular basis, treated or drawn from an appropriate source as a means of assuring it is appropriate for its intended purpose” without any specification of metrics, methods, or frequency of testing. “We stayed away from numbers because we wanted to remain flexible,” recalls Gombas. Moreover, “we were running into some opposition from growers who complained ‘How dare you propose specific guidelines for fresh leafy greens! We’ve been growing these crops all our lives, and we know what to do.’ So at the time, there was still some resistance to changing food safety practices, especially without the science to indicate ‘this is exactly what you should be doing.’”

Although the 2006 industry guidance placed no specific demands on growers, its authors hoped that it would encourage them to pay more attention to food safety. Industry leaders, believing that the new guidance would be taken more seriously if it came from federal regulators, asked FDA officials to co-
author the guidance or to publish it as agency guidance. However, FDA officials, despite having participated extensively in the process of formulating the guidance, were unwilling at that time to adopt it as their own without subjecting it to additional review within the agency.  

### Buyer GAPs and Private Food Safety Auditing

While produce industry committees published voluntary guidelines and government agencies issued guidance, buyers of fresh produce—retail supermarkets, restaurants, and food service companies—also engaged in the development of GAPs. Fearful of the damage that an outbreak could cause to their brands, buyers increasingly included food safety standards in their product specifications. They ensured compliance with these specifications by requiring their suppliers to undergo periodic food safety audits of their operations. The resulting system of private food safety auditing has developed into a global network that governs growers around the world.

Initially, retail buyers considered food safety as part of quality assurance and regulatory compliance. For example, Gale Prince, Corporate Director of Regulatory Affairs from 1979 to 2007 at Kroger, one of the nation’s largest supermarket chains, supervised a staff of field buyers who visited growers to determine whether their produce met government quality grading standards and pesticide regulations and, eventually, whether their operations followed government and industry GAPs. Over time, recalls Prince, Kroger developed “additional specifications for various products” based on the recommendations of in-house experts and outside consultants “that went beyond the government standards.” Other major buyers—including retailers such as Walmart and Costco and restaurant chains such as McDonalds and Taco Bell—employed similar systems.

In implementing these systems, retail buyers—especially supermarkets—increasingly relied upon third-party auditors to oversee their produce suppliers. One explanation for this turn to third-party auditors is that retail buyers lacked sufficient in-house capacity to conduct all of the necessary audits themselves. A typical supermarket carries more than 700 fresh produce items, each of which may have as many as a dozen or more suppliers. “There are just too many suppliers; we couldn’t possibly audit every
single one,” explains John Hansen, who is in charge of food safety for Sprouts Farmers Market, a national supermarket chain.36

A second explanation for increasing buyer reliance on third-party auditors is the nature of the supply chain for fresh produce. To ensure consistent availability of fresh produce throughout the year, supermarkets purchase many items in an auction system, meaning that their suppliers may change frequently. Thus, retailers do know who many of their suppliers are until they purchase items at auction, too late to inspect the suppliers’ cultivation and harvest practices. Similarly, retail supermarkets sometimes buy produce from distributors, so the retailers have no direct relationship with growers. To ensure oversight of growers in these situations, retail buyers include in their product specifications that they will purchase at auction items only from growers and processors who have obtained a third-party food safety audit.37

A third, related, explanation for the turn to third-party auditors is cost-effectiveness. A third-party auditor can spread the cost of travel and other expenses by conducting multiple audits in a single trip to a growing region, resulting in a lower cost per audit compared to the cost of audits by in-house staff whom a retail buyer sends out to audit its one or two suppliers in the region. Similarly, a third-party auditor can generate enough audits in a particular type of operation to develop specialized expertise beyond that of in-house staff tasked with auditing a variety of different types of suppliers. Consequently, retail supermarkets outsource auditing services to reduce costs and obtain a higher level of expertise. On the supplier side, the cost to a producer of shepherding around a different auditor from each of its retail buyers is higher than obtaining a smaller number of third-party audits, each of which typically satisfies multiple buyers.38

A fourth explanation is that retail buyers believe that third-party auditors enhance the reliability of audits. Third-party auditors provide “another set of eyes,” according to Craig Wilson, Vice President for Quality Assurance and Food Safety at Costco, who first retained third-party auditors to complement the company’s in-house auditing program in 1998. Art Davis, a leading food safety consultant, argues that
third-party auditors may be less biased than in-house staff, who typically also have responsibilities to obtain aesthetically appealing or low-cost produce that color with their judgments regarding food safety.\textsuperscript{39}

The scale and scope of private food safety auditing in all sectors of the food industry exploded between 2000 and 2010. In 2011, the FDA inspected 19,073 domestic food facilities and 995 foreign food facilities. The USDA maintained inspectors in 6,000 domestic facilities that produce meat, poultry, and processed egg products. State governments also conducted tens of thousands of food safety inspections each year. By comparison, the Food Safety Service Providers, an industry association representing nine leading private food safety audit firms, asserted in 2011 that its members alone conduct more than 200,000 audits and inspections in over 100 countries each year. Beyond these nine industry leaders, the FDA estimated that there were 568 firms conducting private food safety audits. Based on these figures, it appears that, by 2011, the scale of private food safety auditing activity far exceeded that of all federal and state efforts combined. Reliance on private food safety audits was even greater on farms, where federal and state officials rarely showed up unless they were investigating an outbreak. Primus Labs claimed that it conducted “approximately 15,000 audits … per year for over 3,000 clients worldwide.”\textsuperscript{40}

Growing demand among retail buyers of fresh produce for third-party audits fueled the growth of an increasing variety of audit standards. FDA and industry association GAPs guidance provided the basis for audit criteria. Private third-party auditing firms competing for accounts developed their own branded audits, which typically appealed to retail buyers by offering an array of options ranging from minimal GAPs compliance to more detailed and stringent audit criteria. In addition, individual retail buyers frequently retained their own particular food-safety-related product specifications that audit firms included as addenda to their branded audits. The result was “audit fatigue” among growers who were forced to obtain multiple audits to satisfy the diverse demands of different retail buyers. Some growers were forced to undergo as many as two-dozen audits a year. Art Davis recalls one grower in 2004 who was subjected to six audits in two weeks.\textsuperscript{41}

To consolidate the growing number of audit standards, retail trade associations developed food safety schemes designed to provide a single set of audit criteria for all of their members. To further reduce audit
fatigue, major retailers launched an effort in 2000 to promote convergence among different food safety standards. The International Committee of Food Retail Chains, a trade association, established the Global Food Safety Initiative (GFSI) to define “benchmarks” that set minimum standards for food safety schemes and encourage buyers to accept certification under any scheme that meets these minimum standards.42

GFSI’s demanding benchmarks have created an echelon of high-quality third-party auditing services, and they have reduced the problem of multiple, redundant third-party audits—but they have not eliminated it. Not all retail buyers want to impose the relatively high cost of obtaining a high-quality GFSI audit on every supplier for each product. Smaller retailers may lack the market power to push large suppliers to pay for more expensive audits. Larger retailers may not wish to overburden suppliers who operate small or local farms. Retailers are also concerned that they will end up paying at least part of the high cost of GFSI audits in the form of higher fresh produce prices. In addition, many retailers still insist that audits include an addendum, which may contain particular concerns of the company or more specific standards tailored to a certain type of product. Consequently, audit firms continue to offer a range of audits, only some of which are now GFSI-recognized and many of which continue to include company- or product-specific addenda.43

Suppliers launched their own effort to address the problem of multiple audits. In 2009, the United Fresh Produce Association (created out of a merger of the International Fresh-Cut Produce Association and the United Fresh Fruit and Vegetable Association in 2006) organized the Produce GAPs Harmonization Initiative with the aim of creating a single set of food safety standards that would enable growers to obtain “one audit by any credible third party, acceptable to all buyers.” A committee of 150 food safety and fresh produce experts “reviewed 13 commonly accepted fresh produce food safety standards, identified commonalities and selected the words from each that best suited a common standard, without sacrificing any food safety considerations,” explains Gombas, who conceived and directed the effort. The committee gathered input from a wide variety of stakeholders—representatives from food
companies throughout the supply chain, government agencies, scheme owners, and audit firms—and, in 2011, rolled out a set of standards known as the Harmonized Standards.44

Like retailer-sponsored food safety schemes and benchmarks, the Harmonized Standards have reduced the burden on suppliers of multiple audits, but they have not eliminated the problem. Although some major buyers accept any audit that uses the Harmonized Standards, many buyers accept only audits from particular auditors, or they require their own addenda, or they require GFSI-recognized audits.45

The inefficiency of multiple audits is only one of several criticisms of the private auditing system. Auditors with many years of experience complain that the quality of audits has declined over time. Food safety auditors originally served as food safety consultants. Bill Pursley, former Vice President of Food Safety at the American Institute of Baking (AIB), recalls that when he started working as an AIB food safety inspector in the 1970s, companies would hire inspectors on the companies’ own initiative to assess their regulatory compliance and provide advice about how to improve food safety within their operations. “My mission was not to find all of the problems in the plant but to teach them to find their own problems, to look more closely at their own plants. The mission was education.”46

When companies began using audits to satisfy their buyers, the nature of auditing changed. “The AIB inspection system was originally designed to be an educational tool not a supplier approval system,” explains Pursley. Whereas auditors originally awarded scores and grades to help companies track the quality of their food safety efforts over time, companies increasingly needed scores and grades to satisfy buyer specifications. Companies became more interested in obtaining a passing grade to satisfy their buyers than using the audit process as a means of gaining insight into shortcomings of their own operations and receiving advice about how to address them.47

As the emphasis on scores and grades increased, audit firms and buyers created checklists to provide a consistent basis for scoring and grading. Checklists also provided auditing instructions for newer auditors who lacked the training and experience of older consultants. Before joining United Fresh, David Gombas worked for Campbell’s Soup at a time when all of the company’s supplier audits were conducted by in-house staff. “We went out and audited all of our own suppliers, and we knew, within a half an hour
of walking in, whether or not we going to buy from these folks. We didn’t have any standards, there was no checklist. You knew—you walked in and you talked to the owner and you looked around the facility; you could tell whether or not you wanted to buy from that operation. But when the number of suppliers outgrew the size of our audit team, we started using third-party audits. And so the third-party auditors would go out and we had to give them something to audit to because they weren’t on our own staff. They had their own perceptions, but we knew what we wanted them to look at. So we gave them standards to go audit against … a checklist of what’s important to look for.”

As audit criteria multiplied over time, the checklists became longer and more detailed. Moreover, audits increasingly focused on reviewing company records rather than visually inspecting plant equipment and workers, on the theory that records provide insight into how a company’s food safety program performs over time, whereas walking the plant floor offers only a snapshot on that particular day. The overall result was audits performed by less-well-qualified auditors filling out long detailed checklists based largely on a review of company records. “If you watch the typical auditor go through a plant, it looks like they’re on a freakin’ scavenger hunt because there are so many things that have to be filled out on the checklist, and a lot of it is paper stuff,” explains Dave Theno, a leading food safety consultant with over thirty years of food safety auditing experience. “They’re scurrying around with their heads down on the checklist. But the real way to find out what’s going on in the plant is to watch the people and ask, ‘Are the food safety processes running as they’re designed?’ It’s hard for auditors to see that stuff when they are scheduled for a short period of time and there are a couple of hundred items on their checklist.”

Increasing reliance on scores and grades in fresh produce was fueled by retailers’ need for a quick way to review the growing volume of audits generated by expanding global supply chains that provided a wide selection of fruits and vegetables all year round. The half-dozen in-house food safety staff employed by a major retailer do not have time to do much more than review audit scores and grades and, perhaps, a short audit summary, of the company’s thousands of fresh produce suppliers, some of whom may be submitting more than one annual audit. Retailers’ have created an audit system that generates more food safety information than they can process.
Audit quality also suffered because the rapidly growing demand for audits exceeded the limited supply of qualified auditors. The demands of the job—strenuous physical exertion and extensive travel—exacerbated the shortage. “Auditors are typically away from home four days each week. They work long hours all day sweating in hot production plants. At night they work on reports. It’s hard on families,” explains Gale Prince. Many audit firms resorted to paying independent contractors to perform audits. The more qualified of these were retired food safety managers and government inspectors who often lacked experience in the particular sector in which they were performing audits. Moreover, many older auditors had backgrounds in sanitation but lacked training and expertise in microbiology.51

Even as audit quality declined, audits became more costly. Retail buyers competed with one another to include increasingly onerous food safety requirements—frequently unsupported by any science—in their product specifications. “You’ve got a lot of companies trying to one up each other,” explains former president of Dole Fresh Vegetables Eric Schwartz. For example, “the buffer zones on the ground—it’s not uncommon for a retailer to say ‘I need ten feet between the field and the fence,’ and another retailer will say, ‘Well if that store is at ten feet, I want fifteen.’ There’s a lot of that going on in the industry, and, unfortunately, it has taken on a life of its own. It’s adding a tremendous amount of cost to the industry with no risk reduction.” Competition between audit firms also promoted greater stringency and increased costs. According to David Gombas, “it’s a lot easier for an auditing firm to market that ‘We have tougher standards,’ than to say ‘Our auditors are better than the other guy’s,’” resulting in a continuous “ratcheting up of the stringency of audit standards.” Audits also became less consistent. The growing number of audit checklist items typically provided no metrics, requiring auditors to assign scores based on highly subjective qualitative assessments, which made it difficult for audit firms to maintain consistency among audits.52

Finally, auditors face considerable pressure to keep audit costs down, and this creates a conflict of interest. Suppliers, who pay for audits—fees range from $1,000 to more than $25,000—seek auditors who are likely to award them a score that will satisfy buyers, and they are unlikely to re-hire an auditor whom they perceive to be too tough. “Some suppliers will hunt down the fastest, cheapest, easiest, and least
intrusive third-party audit that will provide the certificate,” explains David Acheson, former FDA Associate Commissioner for Foods who now directs a leading food safety consulting firm. Consequently, auditors competing for accounts have incentive to reduce the cost and burden of audits by spending less time, downplaying food safety risks, and inflating audit scores.53

Marketing Agreements

The 2006 baby spinach outbreak prompted leafy greens industry leaders to try a new approach to regulating food safety on farms. The outbreak left many consumers fearful of eating spinach and other leafy greens—especially bagged produce from California. Wary supermarkets, restaurants, and food service companies “backed away from leafy greens,” recalls Bob Whitaker. For a time, Canada closed its borders to U.S. spinach. In December, the FDA traced another outbreak of illness caused by *E. coli* O157:H7 to shredded iceberg lettuce served by the popular fast food chain Taco Bell, further stoking concerns about leafy greens.54

Desperate to restart production and win back consumer confidence, industry experts began discussing how to improve food safety in leafy greens production. Bob Whitaker hosted informal daily discussions over bagels and coffee in his office at NewStar Fresh Foods among half a dozen food safety managers from leading processors. These discussions quickly expanded to include additional stakeholders—trade association representatives, federal and state regulatory officials, and academic researchers—who formed a working group and developed a draft proposal. Hank Giclas, of the Western Growers Association, organized meetings of leafy greens growers and processors throughout the state at which he presented the draft and obtained feedback, which the working group used to refine the proposal. By the spring of 2007, this process produced the California Leafy Green Produces Handler Marketing Agreement (LGMA).55

The LGMA founders focused on reducing the risk of contamination in growing fields. They began by analyzing the weaknesses within the existing system of GAPs guidance and private audits. To begin with, industry and government GAPs guidance was too vague. GAPs were drafted in general terms to allow for flexibility in implementing them in different types of operations. However, under the increasing scrutiny
of audits, many growers wanted more specific instruction. Gombas recalls that “the growers were complaining: ‘You tell me I should use water of adequate quality, but what does that mean? How do I know if it’s “adequate”? You tell me I shouldn’t harvest produce that has any contamination on it, but how far away from it can I harvest? What’s a safe distance?’”

This lack of specificity, coupled with the voluntary nature of GAPs guidance, led to low rates of adoption among farmers. Drew McDonald explains that industry and government guidance “said things like ‘You should consider testing water. You should consider having a supplier approval program. You should consider reviewing the fields where your products are grown.’” Consequently, “a vast majority of the industry responded, ‘Well, they don’t say that I have to do all this’ or ‘They’re not specifically telling me what to do.’ And so people just went their merry way, saying, ‘You know, it’s just produce. It’s growing in the ground. It’s in the dirt. We’ve been doing it this way for a long time. No one’s gotten sick, so everything’s fine.’” In the wake of the 2006 baby spinach outbreak, the LGMA founders worried that the failure of even a small segment of growers to take food safety seriously could bring down the entire industry.

In addition to their concerns about GAPs standards, the LGMA founders believed that private third-party audits had failed to deliver sufficient food safety improvements on farms. The quality of audits varied widely depending on the training and experience of the auditors. The decentralized proliferation of food-safety specifications by buyers required growers to undergo multiple, largely redundant, audits, which merely increased their costs without improving safety. Suppliers’ insistence that growers hire and pay the auditors created a conflict of interest that undermined public confidence in the whole system.

The LGMA founders addressed the problem of vague standards by attaching quantitative measures, which they called “metrics,” to the GAPs guidance criteria. For example, the LGMA metrics specified testing protocols and thresholds for generic E. coli levels in irrigation water, and for fecal coliforms, Salmonella, and E. coli O157:H7 in compost. Similarly, they defined the minimum radius around animal droppings found in fields within which crops should not be harvested.
The LGMA founders avoided the problems with private third-party audits by relying, instead, on government inspectors from the California Department of Food and Agriculture (CDFA). They also figured out how to make buyers rather than growers pay for the audits and how to ensure near universal adoption of the metrics among growers. The LGMA founders achieved these reforms by creating a marketing agreement.

In the midst of the Great Depression, the federal government passed the Agricultural Marketing Agreement Act of 1937. Simultaneously, the State of California passed the California Marketing Act of 1937. Both acts authorized the creation of marketing agreements. A marketing agreement is a voluntary commitment among a group of agricultural producers of a specific commodity that sets common standards for production volume, quality characteristics, or packaging, with the aim of stabilizing prices. Marketing agreements thus allow agricultural producers to organize in ways that might otherwise violate antitrust laws designed to prevent collusion and price-fixing.60

The LGMA founders created a marketing agreement under the California Marketing Act that set food safety standards for leafy greens growers. The agreement, however, is among leafy greens handlers—defined as “any person who handles, processes, ships or distributes leafy green product for market.” The agreement distinguishes handlers from growers, who produce greens, and explicitly states that the definition of handler “does not include a retailer.” Handlers who sign the marketing agreement commit to purchasing leafy greens exclusively from growers who pass periodic food safety audits of their operations by state inspectors using LGMA standards. In exchange, signatory handlers may display an official mark on their products and their promotional materials indicating membership in the LGMA and CDFA certification of their products. Signatory handlers who violate the terms of the agreement lose their certification and their right to use the mark. Unauthorized use of the mark constitutes an unfair trade practice in violation of state consumer protection law. The LGMA marks the first time that a marketing agreement has been used to promote food safety standards.61

Following public hearings, the CDFA approved the LGMA. To assist the CDFA in the administration of the agreement, the LGMA establishes a California Leafy Green Handler Advisory Board, consisting of
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handler signatories from different growing regions of the state and one representative of the general public, who must be unaffiliated with any industry organization. The agreement authorizes the LGMA Board to contract with the CDFA to provide agency inspectors to perform on-farm audits that assess grower’s compliance with LGMA food safety standards. These third-party government audits are paid for by handlers, who pay an annual assessment that finances the operating costs of the agreement—including government inspections—as a condition of LGMA certification.62

Thus, the LGMA board is a public entity empowered to administer a voluntary agreement among private firms. The rules that govern administration of the agreement have been adopted by the Secretary of Food and Agriculture as state regulations. However, the food safety standards by which the firms agree to abide are private industry standards accepted by the state agency responsible for administering the agreement. This acceptance means that the CDFA agrees to provide audits against those standards. It does not, however, give the standards the status of agency regulations.63

The LGMA has achieved nearly universal adoption of its standards among California leafy greens growers by making handlers the subjects of the marketing agreement. A small group of handlers have a particularly high stake in preventing outbreaks, and they command a level of market power that gives them considerable influence over growers. Although outbreaks can affect everyone in the leafy greens industry, they pose the greatest threat to handlers who produce leading brands of fresh-cut bagged produce. These companies lack the anonymity among consumers that shields growers and handlers of unmarked whole produce. Packaging bearing a brand name makes it easier to identify a particular company as the source of an outbreak and tends to focus unwanted media attention on the company, even if contamination originates with a grower upstream in the supply chain. Thus, the 2006 outbreak is popularly known as the Dole baby spinach outbreak, not the Paicines Ranch or Natural Selection Foods baby spinach outbreak. This vulnerability explains why food safety managers at leading brand name producers of fresh-cut bagged greens—for example, Bob Whitaker at NewStar Fresh Produce, Drew McDonald at Taylor Farms, and Eric Schwartz at Dole Fresh Vegetables—initiated the LGMA. A few of these large brand name handlers dominate the market. In 2006, Fresh Express (owned by Chiquita)
accounted for $41% of all bagged, fresh-cut salad sales, and Dole accounted for 31%. Along with the next two leading firms, Ready Pac and Earthbound Farms, four companies controlled 86% of the market. Thus, a small group of highly brand-sensitive handlers who controlled most of the market had both the motivation and the leverage to encourage widespread adoption of the new standards among growers. Six months after approval of the LGMA, fifty-one handlers, responsible for more than 99% of the leafy greens produced in California, had joined the LGMA.64

The LGMA founders insisted, from the outset, that metrics should be supported by science. “The guiding principle in developing the LGMA was that everything had to be based in science,” recalls McDonald. The LGMA founders took a “three-tier approach” to developing metrics. The introduction to the LGMA standards document explains that “[a] comprehensive literature review was conducted to determine if there was a scientifically valid basis for establishing a metric for the identified risk factor or best practice. If the literature research did not identify scientific studies that could support an appropriate metric, standards or metrics from authoritative or regulatory bodies were used to establish a metric. If neither scientific studies nor authoritative bodies had allowed for suitable metrics, consensus among industry representatives and/or other stakeholders was sought to establish metrics.”65

Given the dearth of scientific studies directly related to microbial contamination in farming operations, the LGMA relies heavily on established standards from other areas of regulation. For example, in developing a 400-foot standard as the minimum buffer between cattle feeding operations and crops, Trevor Suslow recalls that “there were no scientific studies that specifically addressed the transfer of pathogens from a feeding operation to a lettuce field.” There were, however, “studies that dealt with the movement of what’s called fugitive dust from these operations, and you have local ordinances that use this data to establish 400-foot setback distances from residential areas. There wasn’t a specific data set that specifically addressed produce safety, but we drew on the best available science that gave us some point of reference for a starting point.” In developing the metric for irrigation water of “adequate quality for its intended use,” Gombas recalls that “there was no science to come up with a number. So the closest
thing that we could come up with was, ‘Well the EPA is saying that these recreational water standards are safe enough to swim in, and, if it’s safe enough to swim in, it must be safe enough to irrigate with.”’

The LGMA founders anticipated that the metrics would develop over time as the relevant science advanced. The LGMA standards guide, created by industry and accepted by the California Secretary of Food and Agriculture, “has been and continues to be an evolving and live document, as new information comes to light through scientific research or from other sources,” explains Suslow. The LGMA Board established a Technical Committee, composed of food safety managers and consultants, to review proposed changes to the metrics and make recommendations to the Board. To support scientific research related to food safety on farms, the Produce Marketing Association partnered with the University of California at Davis to establish a Center for Produce Safety in 2007. The aim of the Center was to fund and disseminate “hands on, boots-on-the-ground research to begin filling some of those knowledge gaps so that, where we were just surmising what a best practice should be based on logic, we might be able to get some data to actually give it more direction,” explains Whitaker, who estimates that in its nine years of operation, the center has funded “about 120 projects to the tune of about $18 million,” raised from industry.

The LGMA founders believed that they had created a model that could be applied to the regulation of leafy greens nationwide. In October 2007, having successfully supported the establishment of a similar leafy greens marketing agreement in Arizona, they asked the USDA Agricultural Marketing Service (AMS) to consider a national leafy greens marketing agreement. In response, the AMS published an Advance Notice of Proposed Rulemaking to obtain feedback from stakeholders, who submitted more than 3,500 public comments. In June 2009, a coalition of industry associations submitted a proposal for a national leafy greens marketing agreement to the AMS and requested public hearings, which the agency held in September and October. During nine days of hearings in seven cities around the country, 120 individuals testified, generating 4,935 pages of testimony. In April 2011, the AMS published a Proposed National Marketing Agreement Regulating Leafy Green Vegetables and invited comments by the end of July.
The proposed national leafy greens marketing agreement (NLGMA) was modeled on the California LGMA. The proposal contemplated reliance on standards developed by industry experts and accepted by the AMS. Handlers that complied would earn the right to display an NLGMA certification mark. Assessments from signatory handlers would fund monitoring by AMS inspectors or state inspectors approved by AMS. A Board of industry representatives would administer the agreement with advice from a Technical Review Committee. Board decisions would be subject to the USDA Secretary’s approval.

Some opposition to the NLGMA came from within the leafy greens industry. Small and mid-size farmers argued that the NLGMA, like its California predecessor, was designed to serve the interests of large fresh-cut processors. David Runsten, Director of Policy and Programs for the Community Alliance with Family Farmers (CAFF), a trade association representing small and mid-size California farmers, testified against the NLGMA at a USDA hearing. He asserted that a small group of processors dominated the California LGMA Board and created safety standards designed specifically to reduce the risk of contamination in monoculture growing operations that supplied the fresh-cut industry. Runsten argued that a crop-by-crop approach to regulating food safety on farms—one set of rules for greens, another for tomatoes, and a third for melons—might be suitable for large-scale commodity agribusiness but imposed unnecessary burdens on small and mid-size farms that grew a variety of crops, some of which grow as many as one hundred different crops in the course of a year. A separate set of metrics for each type of crop imposed a multitude of regulatory requirements on diversified farms, which, unlike large operations, could not take advantage of economies of scale that made it easier to absorb the costs of compliance.

Moreover, LGMA metrics that required buffer zones between crops and non-crop vegetation and animals was “particularly burdensome for small farms that include animal production or that try to integrate farming practices with protective environmental or ecological practices.” LGMA imposition of “clean fields” metrics, complained Runsten, “also had a spillover effect in other crops, even those not eaten raw, such as potatoes, artichokes, and Brussels sprouts. After 20 years of planting hedgerows and other conservation measures on farms, CAFF finds itself in direct conflict with food safety auditors who say that ‘food safety trumps the environment.’”
Runsten insisted that most outbreaks linked to lettuce and spinach had been traced back to fresh-cut, bagged products, not whole-head or bunched leafy greens, and that, consequently, any national marketing agreement should be limited to the fresh-cut market and apply only to growers supplying processors. The NLGMA threatened to empower fresh-cut processors to shut out of the wholesale market any farmer who refused to comply with excessively stringent metrics that imposed unnecessary precautions on small and medium growers. “Metrics that might be appropriate to the large commercial operations with entire fields of one crop destined to be processed and to sit in a bag for weeks are inappropriate for smaller, more diversified producers who are supplying a local wholesale market.” Runsten was careful to emphasize that CAFF did not oppose regulation. “CAFF has always supported an effort to develop a set of basic food safety practices—such as monitoring prior land use and activities on adjacent land, periodically testing water sources, or having farm workers wash their hands after using the toilet—that would be applicable to all farms growing produce.” However, he insisted that “specialized rules to control risks for special markets—such as the fresh-cut processing industry—should be confined to farms producing for those markets.”

Opposition to the NLGMA came also from consumer advocates. They argued that marketing agreements offered a poor substitute for government regulation. “As a voluntary program, members can simply elect not to participate, and there is no penalty for doing so beyond the removal of a marketing seal on their packaging,” objected Caroline Smith DeWaal, the Director of Food Safety at the Center for Science in the Public Interest at a 2009 Congressional hearing on leafy greens marketing agreements. “[I]f Good Agricultural Practices (GAPS) are not required on every farm … the door remains open for contaminated produce to reach consumers,” complained Elisa Obadashian, the West Coast Director for Consumers Union in comments on the AMS’s 2007 Advanced Notice of Proposed Rulemaking.71

Consumer advocates criticized the legitimacy of marketing agreements, alleging a lack of transparency, stakeholder participation, and public accountability. Obadashian complained that the California LGMA metrics had been developed “behind closed doors and without public comment. The
industry appointed itself as the safety oversight board, including some of the very companies, such as Dole, which have been accused of marketing contaminated leafy greens.”

Consumer advocates also challenged the effectiveness of marketing agreements, citing outbreaks traced back to California leafy greens following the implementation of the LGMA. “Industry self-regulation seldom protects consumers,” declared Obadashian. “Clearly, the use of a voluntary marketing agreement, developed by the very people who brought spinach and bagged salad mix contaminated with a particularly virulent strain of *E. coli* (O157:H7) to market, is not the best way to restore consumer confidence or ensure that another terrible outbreak does not occur.”

DeWaal objected to entrusting oversight of a food safety program to the USDA’s AMS. She explained that “AMS is charged with ‘facilitating the competitive and efficient marketing of agricultural products.’ It does so by overseeing ‘commodity programs.’ These programs provide standardization, grading, and market news services for related commodities.” She cited the testimony of David Shipman, Acting Administrator of AMS, who had stated in an earlier Congressional hearing that “[t]he mission of AMS is to facilitate the strategic marketing of agricultural products in the domestic and international marketplace. AMS is not a food safety agency.”

Obadashian and DeWaal argued that existing GAPs guidance and marketing agreements had proven ineffective in ensuring the safety of leafy greens. Instead, they advocated mandatory federal regulations. “The very process of rulemaking offers an opportunity for notice and comment among all stakeholders, with the aim of ensuring … the public health …. Such notice and comment is of course absent from the boardrooms where today’s private contracts are drafted,” stated DeWaal. Responsibility for developing and enforcing such regulations should be assigned to the FDA, whose mission, in contrast to that of AMS, was consumer protection rather than industry marketing. “Congress should act to curtail the trend toward use of marketing orders by providing FDA with the authority and resources it needs to carry out its food safety responsibilities,” she concluded.

Congress eventually heeded these calls to charge FDA with the task of developing and implementing mandatory on-farm food safety regulations for fresh produce when it passed the Food Safety
Modernization Act (FSMA) in December 2010. As the FDA was developing those rules, the AMS quietly abandoned its efforts to establish a national LGMA. In December 2013, the agency published a brief notice in the Federal Register terminating its NLGMA rulemaking procedure.73

The FSMA Produce Safety Rule

In his March 14, 2009 weekly radio address, two months after his first inauguration, President Obama declared that “[t]here are certain things that only government can do. And one of those things is ensuring that the foods we eat … are safe and don’t cause us harm.” Citing the baby spinach outbreak of 2006 and a peanut butter outbreak that was unfolding as he took office, Obama announced the creation of a Food Safety Working Group co-chaired by the Secretaries of Health and Human Services and the USDA and composed of senior officials from the FDA, FSIS, CDC, and other federal agencies with instructions “to report back to me with recommendations as soon as possible” about “how we can upgrade our food safety laws for the 21st century.”74

The President’s Food Safety Working Group reported back “key findings” in June. Among the priorities it listed, the Working Group pledged that “by the end of the month, FDA will issue commodity-specific draft guidance on preventive controls that industry can implement to reduce the risk of microbial contamination in the production and distribution of tomatoes, melons, and leafy greens. These proposals will help the Federal government establish a minimum standard for production across the country. Over the next two years, FDA will seek public comment and work to require adoption of these approaches through regulation.” In August 2009, the FDA published a notice in the Federal Register requesting comments on draft commodity-specific guidance documents on tomatoes, melons, and leafy greens.75

Although it appeared from the outside that these draft guidance documents grew out of the President’s Working Group, they were part of FDA’s ongoing efforts to respond to outbreaks dating back to the early 2000s. Following publication of its initial 1998 GAPs guidance for fresh produce, the FDA had pledged in its 2004 Produce Safety Action Plan to work with industry to develop commodity-specific guidance, and FDA experts had participated in the development of the industry’s 2006 commodity-specific leafy
greens guidance. Additionally, the FDA had developed guidance on processing fresh-cut produce between 2004 and 2008 and had issued a notice in the Federal Register in September 2008 soliciting comments on how to improve the agency’s GAPs guidance. The FDA’s 2009 draft guidance, far from a new initiative, reflected “the evolution of our thinking between our initial GAPs guidance in 1998 and that point in time,” recalls the FDA’s Michelle Smith who started at FDA in 1991 and has been involved in the agency’s fresh produce food safety efforts since President Clinton’s 1997 Food Safety Initiative.76

While the FDA was developing these guidance documents, the Center for Science in the Public Interest petitioned the FDA in November 2006, following the baby spinach outbreak, and again in 2008, to issue mandatory on-farm food safety regulations for fresh produce. DeWaal had complained that the spinach outbreak demonstrated that FDA reliance on guidance was “weak-kneed” and that “[n]o one is really in charge of food safety on the farm,” since the agency “can only suggest but not enforce. They need direction from Congress to address standards on the farm.”77

Starting in 2008, various members of Congress introduced food safety reform legislation in both the House and the Senate. In the final days of December 2010, both chambers passed the Food Safety Modernization Act (FSMA), which President Obama signed on January 4, 2011. The new law instructed FDA to issue binding food safety regulations for the production of fresh produce—what became known as the FSMA Produce Safety Rule, which the FDA issued in November 2015.78

In some respects, the FDA’s FSMA Produce Safety Rule is a continuation of efforts by industry and the agency to develop GAPs guidance. In crafting standards and metrics for the new rule, the agency drew heavily on the “experience over time and the interactions we’ve had with industry,” explains Smith. “Industry folks really put a lot of effort into educating us—for example, different groups provided us opportunities to tour farms.” California LGMA founders, in particular, take credit for shaping the Produce Safety Rule. “FDA has, for many years, been involved in the industry,” says Drew McDonald, and consequently “FSMA, by and large, got it right. I mean, they were listening. They wrote up what many of us in the industry were already doing, the exact language if you really do a comparison. In the produce rule, they borrowed so much—and I take it as a compliment—from the leafy greens metrics. So they
really got it right.” According to David Gombas, “when the FDA created the Produce Safety Rule, they looked at all the different standards out there, and the only one that had numbers was leafy greens. So when they were trying to figure out what is water of ‘adequate quality,’ the only one that had a standard was leafy greens, so they adopted the standard from leafy greens.”

Like earlier industry and agency efforts, FSMA calls for “science-based minimum standards” for the production and harvesting of fresh produce, and the agency’s Produce Safety Rule focuses on water quality, soil amendments, animal intrusion, worker hygiene, and harvesting equipment. The rule offers a mix of specific quantitative metrics and general guidelines. For example, the water standards prescribe testing methods and threshold values for *E. coli*. By contrast, the animal intrusion standards require growers to “[a]ssess the relevant areas” in growing fields “as needed” and “if significant evidence of potential contamination is found,” to “take measures reasonably necessary” to avoid harvesting the contaminated produce. The agency promises to issue future guidance to assist farms in complying with the regulations.

In other respects, the FDA’s FSMA Produce Safety Rule marks a departure from the past. The Produce Safety Rule abandons the agency’s efforts to develop commodity-specific GAPs, driven by repeated outbreaks of what the agency came to consider “high-risk” crops, such as leafy greens, tomatoes, and melons. Instead, the new rule takes an “integrated approach,” which prescribes the same standards for all fresh produce. The agency explains that its new rule “provides a whole farm approach rather than commodity-specific measures, which would be challenging for farms that grow multiple crops.” Moreover, the agency views its prior focus on outbreaks as reflecting too reactive and too narrow an approach to regulating food safety. Reliance on outbreak data meant that the agency took action only after consumers fell ill, and its efforts addressed only those risks associated with illnesses traced back to a particular food. FDA data collection from farms associated with outbreaks simply reinforced its exclusive attention to known risks. By contrast, FSMA mandates a “prevention-based approach” to food safety capable of protecting consumers not merely from a narrow range of known risks following an outbreak but from a broad range of suspected risks before anyone gets sick. Moreover, although the FDA’s
integrated approach rejects commodity-specific GAPs, it does not impose a one-size-fits-all set of standards on every grower and every crop. The new regulations allow for various means of compliance in many cases; they provide procedures for obtaining variances, and they exempt certain types of growers and products altogether.  

The most radical departure marked by the FSMA Produce Safety Rule was the shift from guidance to mandatory standards. In the face of FSMA’s Congressional mandate to issue binding rules, the FDA’s 2009 draft commodity-specific guidance documents for leafy greens, tomatoes, and melons remained unpublished. Smith believes that the shift from voluntary to mandatory standards had roots in both industry and government. “The initial response to regulating the industry was guidance, and that was fine with everyone. Around the time of the spinach outbreak, some folks started shifting toward being supportive of regulation, including some industry groups who, in advance of FSMA, sent letters to Congress saying that they would support produce regulation because, when an outbreak happens, it negatively impacts the entire industry. So, over time, support for regulations dealing with best practices on farms was growing. And it was FSMA that gave us the final push and direction to actually do it.”  

FSMA’s mandate that the FDA issue binding regulations for farming operations raised questions about the agency’s capacity to monitor and enforce compliance. Historically, FDA inspectors had visited farms only as part of outbreak investigations. It seemed highly unlikely that Congress would appropriate sufficient funds to enable the agency to routinely inspect the nation’s 2.2 million farms. Peter Barton Hutt, a former FDA Chief Counsel known as “the dean of the food and drug bar,” opined that “the lack of reality in the statute is staggering.” Roald Doering, former administrator of the Canadian Food Inspection Agency, voiced his deep skepticism about FSMA’s success, declaring that “[t]he Americans laboured long and hard and delivered a mouse. … There are lessons here for Canada. … Don’t legislate what you can’t enforce.”  

The FDA responded to doubts about its capacity to enforce the Produce Safety Rule by explaining that FSMA created a new approach to industry regulation that would not require comprehensive government inspection or enforcement. “[T]here is no reasonable expectation FDA will have the
resources to make routine on-farm inspection a major source of accountability for compliance with produce safety standards,” the agency explained in a 2014 publication. From the outset, the agency insisted, “Congress envisioned a different role for FDA on produce farms compared to food facilities.” Whereas FSMA mandated specific inspection frequencies for FDA oversight of food processors, the legislation made no mention of inspection frequency for fresh produce growers.84

The agency was “reinventing” itself, said Michael Taylor, the FDA Deputy Commissioner for Foods and Veterinary Medicine. “Historically we’ve had a tradition of enforcement at facilities, and it’s important, but the shift we’re undertaking is to understand that the purpose is not enforcement per se, but to get high rates of compliance with the standards,” Taylor explained in a 2014 speech to the United Fresh Produce Association. “We’re really focusing on outcomes. We’re looking at systems and how we can work with the vast majority of operators who want to produce safe food and to get compliance on a voluntary basis, and that’s the outcome that matters. That’s a fundamental reorientation of our approach to our oversight.” In a posting on the agency’s FDA Voice blog, Taylor explained that the FDA planned to work “in close collaboration with other government agencies (federal, state, local, tribal, and foreign), the food industry and other stakeholders” to supplement its limited inspection and enforcement resources. The agency would reserve its own inspection resources for “high-risk” industry sectors. In addition, the agency would issue new guidance to clarify standards, and it would conduct “outreach and technical assistance to facilitate voluntary compliance.” The agency pledged to “educate before we regulate.” In explaining its proposed Produce Safety Rule in 2013, the agency wrote that “[w]e anticipate that compliance will be achieved primarily through the conscientious efforts of farmers, complemented by the efforts of State and local governments, extension services, private audits and certifications, and other private sector supply chain management efforts.”85

The FDA’s heavy reliance on risk-based inspection, supply chain management, and voluntary compliance suggests that, in practice, the FSMA Produce Safety Rule may be less of a departure than initially anticipated from the agency’s earlier reliance on commodity-specific guidance. In contrast to President Obama’s insistence prior to the passage of FSMA that “only government” can ensure “that the
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foods we eat … are safe and don’t cause us harm,” Taylor told the audience at a 2012 food safety conference that “FSMA recognizes the primary responsibility and capacity of the food industry to make food safe” and “the complementary role of government.”

The challenges of inspection and enforcement also reveal that the FSMA Produce Safety Rule shares with the California LGMA a hybrid public-private structure. The two approaches are, in this sense, mirror images of each other. The LGMA relies on government inspectors to audit compliance with private industry standards. The Produce Safety Rule relies on private auditors to audit compliance with government standards.

The publication of the Produce Safety Rule has raised questions about whether the FDA’s new standards will simply add to the “audit fatigue” suffered by growers already subject to multiple GAPs audits and, in the case of California leafy green growers, LGMA certification. The FDA explains that its Produce Safety Rule sets mandatory minimum standards for growing and harvesting fresh produce, and the agency recognizes that suppliers and marketing agreements may subject farmers to different and, in some cases, more stringent requirements. Although the FDA has insisted on establishing its own standards and oversight system, and it has, for the present, refused to recognize private certification as a substitute for compliance with the Produce Safety Rule standards, the agency believes that private standards are likely to facilitate compliance with government standards. In response to comments, the agency explained that “over time, we expect that certification programs and food safety programs will develop tools to demonstrate the alignment of their provisions with FDA requirements,” so that “[t]o the extent that certification schemes or food safety programs are consistent with the produce safety regulation, then compliance with those schemes or programs could be relevant to compliance” with the Produce Safety Rule. The agency did not further specify what, exactly, “relevant” means here. It appears that the agency hopes its new standards will serve as a benchmark for private schemes and a harmonizing influence. Whether it is more successful than GFSI and the Harmonized Standards remains to be seen.
Liability and Recall Insurance

Bill Marler, the nation’s best-known foodborne illness plaintiffs’ attorney, knew about the Dole baby spinach outbreak almost two weeks before the FDA issued its warning to consumers to avoid fresh spinach. “It was Labor Day weekend and I was on the Oregon coast with my two daughters learning how to surf,” recalls Marler. “Earlier that week, my office had received calls from a mom in Wisconsin with two children in the hospital with Hemolytic Uremic Syndrome [a sign of E. coli O157:H7 infection]. She called because she was convinced that it was Dole baby spinach, still in her refrigerator, that caused her kids to get sick, and she felt that the Health Department wasn’t paying attention to her. That was not an unusual call for us to get, and we sent her a typical packet for prospective clients. Then, later in the week, before I went down to the Oregon Coast, we received another call from a family in Utah with two kids sick from E. coli. At that point, I had not yet connected that case to the one in Wisconsin. But then, on the weekend, while I was in Oregon, I got an email on my Blackberry that the office had received another call, this one from a woman in Salem, who said that she had been infected with E. coli, she had just gotten out of the hospital, and she had eaten Dole baby spinach. I was like, ‘Damn. There’s a nationwide outbreak.’”

“Over that weekend, I emailed a few people in public health saying ‘Hey, I’ve just gotten three phone calls—two of them I.D.-ing Dole baby spinach—all in the same time frame. Are you seeing anything?’ but I got no response. So on Tuesday, after the Labor Day holiday, I started emailing reporters, saying ‘I think there’s a nationwide outbreak going on. You need to start poking health departments.’ Then I got a call towards the end of that week from an epidemiologist in a state that had cases. He told me that there was a nationwide E. coli outbreak, but he did not tell me the product name.”

Unable to confirm his suspicions about the source of the outbreak, Marler nevertheless filed a lawsuit on behalf of the Salem victim against Dole on September 14, the day before the FDA issued its warning. “I was thinking to myself, I’m pretty sure I’m right, but if it’s not really Dole, I’m going to look pretty stupid,” Marler recalls. Six days later, Marler’s suspicion was confirmed. On September 20, the FDA
announced that lab results from New Mexico found the outbreak strain of *E. coli* O157:H7 in a package of Dole baby spinach. Marler eventually filed seventy-six lawsuits against Dole and its suppliers on behalf of victims of the 2006 baby spinach outbreak. He settled all of them for undisclosed amounts. Marler negotiated the settlements with the insurance carriers for Dole, Natural Selection Foods, the company that processed and packed the contaminated baby spinach for Dole, and Mission Organics, the grower that supplied Natural Selection with spinach from a number of fields, including the one leased from the Paicines Ranch, where the contaminated lot of spinach was grown and where investigators suspected the contamination originated.\(^9^0\)

Plaintiffs’ attorneys and liability insurers have a symbiotic relationship. On one hand, lawsuits filed by plaintiffs’ attorneys expose companies to liability, which creates demand for liability insurance. On the other hand, liability insurance provides funds for paying judgments and settlements that motivate plaintiffs’ attorneys to file lawsuits. Liability insurance is key to the “collectability” of a tort claim—that is, “the defendant’s ability to pay and the facility with which the defendant can be made to pay,” according to leading insurance law scholar Tom Baker. For most plaintiffs’ attorneys contemplating litigation, “liability insurance is the only asset that plaintiffs can count on collecting.”\(^9^1\)

In addition to liability coverage that compensates victims of foodborne illness, some insurers also sell recall insurance, which compensates food companies for losses associated with recalling a product that the company suspects may be contaminated. Recall insurance covers the costs of pulling a product off of store shelves, collecting it, and destroying it. Some policies also cover associated business losses when buyers reduce or cancel purchases, or when damage to a company’s brand reduces its sales, as well as the costs of rehabilitating a product. At least one insurer offers such coverage even when a contaminated product of another company causes the policyholder to lose business.\(^9^2\)

Insurance companies not only play an essential role in compensating foodborne illness victims and food companies; they also play an emerging role in reducing the risk of contamination. As Baker explains, “[o]nce insurers accept the financial responsibility for civil liability, they not only have an incentive to manage the defense and settlement of liability claims, but they also have an incentive to
reduce the likelihood that those claims arise in the first place.” A number of insurance industry practices have the potential to reduce the risk of accidents that give rise to liability.93

By means of risk selection and risk pricing, insurers create incentives for companies seeking insurance to reduce the risk of accidents. When a company seeks to obtain insurance, it will typically contact an insurance broker help it find appropriate coverage, or the company may approach an agent representing a particular insurer. When the company applies for insurance, an employee of the insurer known as an underwriter assesses the magnitude of the risks for which the company seeks coverage to determine whether it would be profitable for the insurer to sell the company an insurance policy and, if it would, how much to charge in premiums.94

In deciding whether to insure food companies and how to price policies, underwriters seek information about the quality of applicants’ food safety management systems. Underwriters obtain initial information from brokers and agents, who generate risk-profiles of applicants as part of helping them obtain suitable coverage. For example, “in California’s Central Valley area, there are a number of brokers and agents who are known to specialize within the farm community,” explains Jack Hipp, a longtime senior executive at Fireman’s Fund, now part of Allianz Global, which insured Dole, Natural Selection, and Mission Organics during the 2006 baby spinach outbreak. Typically, a broker or agent “will gather information on the risk … so that they can then look for carrier matches and make recommendations about the types of coverage.” The brokers “are familiar with the food industry, so they know what the issues are within the industry,” says Mike Johnson, an underwriter at Nationwide Agribusiness, an insurer of Mission Organics in the 2006 baby spinach outbreak.95

In addition to reviewing broker and agent risk profiles, the underwriter will investigate the company’s reputation, whether it has been associated with any prior outbreaks, and its history of prior insurance claims. “If a company has a poor loss record because of frequent contamination events, then they’re going to pay higher premiums, or the insurer may decide not to insure them,” says Ed Mitchell, the Chief Underwriting Officer for recall insurance at XL insurance. Underwriters also review the company’s third-party food safety audits and send the insurer’s own in-house risk experts, or hired consultants, to inspect
the company’s operations. “We have food safety experts who give us an idea as to the quality of the account,” explains Johnson."

Risk selection and pricing are ongoing. According to Doug Becker, the Senior Director of Underwriting at Nationwide Agribusiness, his office periodically sends risk management consultants to review clients’ operations. “After a policy is issued, if the risk management consultant goes out and identifies that there is risky behavior going on, he will make recommendations to reduce that exposure and then report back to the underwriter about whether those recommendations were followed. If the client doesn’t follow it, that may affect their premium upon renewal or their actual renewal.”

Insurers have developed underwriting guidelines to standardize their underwriting practices, and they subject their underwriters to one or more layers of management oversight. “The underwriter works within a set of underwriting guidelines,” explains James Derr, a risk management expert at XL. Underwriters’ risk assessments are typically subjected to “a quality assurance review that takes place at the next level of underwriting, just to make sure that we have carefully evaluated the liability potential.”

Food companies seeking insurance want to qualify for that insurance, and they want the best price they can get. Risk selection and risk pricing by insurers give those companies incentives to practice a level of food safety that conforms to the insurers’ underwriting guidelines. Conformity with these guidelines requires compliance with government and industry GAPs standards. According to Hipp, assessing an application for insurance involves “surveying the actual operation to determine how well they comply with the various industry, proprietary, and state safety controls.”

Insurance companies gain experience and build expertise in understanding food safety risks through claims management. When a policyholder files an insurance claim, an employee of the insurer called a claims adjuster investigates the claimed loss, measures it, and negotiates any payments. “Risk knowledge comes from experience,” says Mitchell. “We have paid hundreds of claims and been involved with hundreds of incidents since we started. So we have gathered data that allows us to identify trends. … When a company applies to us for insurance, they have to provide us with quite a lot of information, and that will allow us to make an assessment of the risk against the various metrics that we use to price the
risk.” Claims management provides feedback that helps make underwriting more sophisticated, explains Hipp. “Our underwriters were able to learn immensely from the Dole case through our claims people, and the legal, medical, and scientific experts that the claims people work with in litigation. You can’t duplicate that; you can’t buy it elsewhere. The underwriter learns from a claim why the loss occurred and how best to avoid it in the future. You can apply model data all you want, but without the unique insights you get from real world experience, that’s only part of the equation, and you’re probably missing some very unique aspects of underwriting a risk.”

In addition to risk selection and risk pricing, another means that insurers have to reduce the risk of accidents is contract design. Insurance contracts include a variety of terms and conditions that provide policyholders incentives to take precautions. For example, insurers may limit coverage using deductibles or exclusions, leaving policyholders exposed to liability for up to a certain amount of money or for certain types of conduct not covered by the policy. Deductibles and exclusions counteract any tendency that a policyholder might have to relax its level of care in reliance on insurance coverage, a problem known as “moral hazard.”

With the benefit of experience and increasing expertise, insurance companies have begun to tailor the terms and conditions of their policies to reduce the risk of contamination in food production. According to Hipp, some companies use warranty terms, under which a food company is covered only if it meets the terms of the warranty. For example, “You [the food company] warrant that you are getting third-party inspections on a quarterly basis and, if you are not, then there is either no coverage or reduced coverage.”

A third means that insurers have to reduce the risk of accidents is loss prevention in the form of providing risk management advice to companies on how to avoid losses. “We set aside a portion of the premium that our clients pay us for what we call ‘risk engineering work,’” explains Mitchell. This involves hiring an outside consultant to “audit overall food safety systems, looking for gaps or areas of improvement, and then spending the money that we’ve set aside working with [the client] to improve
their food safety.” Offering risk-management consulting services makes an insurer more attractive to clients as they compete against other insurers, and it helps insurers reduce the risk of claims.103

Insurers have become increasingly sophisticated in their understanding of food safety standards, which has improved their capacity to select and price risks, craft safety-enhancing contract terms, and provide practical advice to clients about risk reduction. “After the Dole spinach outbreak, I led an intensive ramp-up of farm and agricultural-related expertise around foodborne illness, and ran a number of internal seminars for our underwriting, loss control, and claims personnel around everything from microbiology to safety controls and engineering to claims management that would ensure the increased expertise that we needed to really successfully underwrite in that arena,” recalls Hipp. Among the staff members in the seminars organized by Hipp were “actuaries, who need to understand risk as part of their pricing” of insurance policies. Hipp “brought people in from the outside to teach these seminars—lawyers, scientists, government personnel”—the same constellation of experts from industry, government, and academia working on food safety standards for GAPs audits, marketing agreements, and government regulatory programs.104

Have Private Audits, Marketing Agreements, Government Regulations, and Insurance Improved Food Safety?

Available data suggest that efforts to improve on-farm food safety in the fresh produce sector have increased the adoption of GAPs. However, the data do not disaggregate the contribution of any one particular approach. Moreover, it remains unclear whether an increase in the adoption of GAPs has reduced the rate of foodborne illness.

A number of surveys assess the prevalence of on-farm food safety measures. Unfortunately, most of these are local or regional and provide data for only a single point in time. Some longitudinal insight is provided by annual reports of the California LGMA, which document increasing rates of compliance with LGMA standards each year since 2008. National perspective can be gleaned from a 1999 USDA study of fruit and vegetable growers in 14 states, which assessed the use of GAPs in the cultivation of 30 fresh
produce items. The USDA recently conducted follow up national surveys of fruit and vegetable growers in 2015 and 2016, but the agency has not yet published the results. Aside from the prevalence of food safety measures, a second group of surveys provide data on the costs of compliance. For example, one survey of California leafy greens growers in 2008 and 2009 measured an increase in compliance costs over time, finding that respondents’ seasonal food safety costs more than doubled following implementation of the LGMA.105

Taken together, these data provide some evidence regarding the effectiveness of efforts to promote the adoption of GAPs. The most recent USDA national surveys are likely to indicate that the number of growers implementing GAPs has increased since 1999. Increasing rates of compliance and increasing compliance costs among California leafy greens growers subject to LGMA metrics suggest that an increasing number of these growers are implementing GAPs or that they are implementing with greater rigor GAPs that they used prior to the LGMA.

However, given the concurrence of pressure to adopt GAPs from different sources—buyers, the LGMA, government, and insurers—existing studies cannot attribute this increase in adoption or rigor to any particular approach. For example, the LGMA compliance cost study acknowledges “the varying degrees to which [growers] were already in compliance with the LGMA best practices,” and cautioned that “some of the costs reported by the respondents as LGMA modification costs could relate to expenses incurred to comply with other food safety programs, such as those of private third-party food safety auditors….” Similarly, two agricultural economists at the University of Maryland conducted a national survey in 2015 of 394 fruit and vegetable growers and found that a majority of respondents already employed most of the food safety practices prescribed by the FSMA Produce Safety Rule prior to its implementation.106

Moreover, even granting that some of the data provide evidence that one or more of the efforts to improve on-farm food safety increased the adoption or rigor of GAPs, this does not amount to evidence that these efforts have reduced the risk of foodborne illness. Experts have suggested that GAPs reduce the risk of contamination or reduce microbial counts on contaminated produce, although even this is difficult
to prove. According to a review of the effectiveness of the LGMA commissioned by the LGMA board and the Western Growers’ Association, a distinguished panel of four leading food safety experts “expressed confidence that the [LGMA] Guidelines have likely contributed to reducing the human pathogen contamination risk in leafy greens, although some struggled with finding supportive data to prove their general positive sense of a decreased risk.” However, even data proving that increased GAPs adoption or rigor has reduced the risk of contamination would not be sufficient to show that GAPs have reduced the rate of illness.107

Some observers claim that GAPs have reduced or eliminated the recurrent large outbreaks associated with leafy greens. California LGMA CEO Scott Horsfall asserts that “there are fewer *E. coli* outbreaks and illnesses, and regulators and folks who track these things have been very quick to say that the steps taken by the industry, including the LGMA, have led to these kinds of improvements.” Bill Marler similarly opines that “if success is measured by a lack of spinach outbreaks of the size that we’ve previously seen, I would say that looks like success.” However, such generalizations are complicated by the rise and fall in the number of outbreaks traced back to many commodities subject to GAPs, such as outbreaks attributed to contaminated spinach, which have fluctuated since 1998, as illustrated in figure 4.1.

**Figure 4.1**

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![Spinach Outbreaks 1998-2015](image-url)
Consumer advocate Caroline Smith DeWaal seized on this point in 2009 Congressional testimony, asserting that the California LGMA “has not proven effective, as indicated by several recent outbreaks. In May 2008, bagged Romaine lettuce sickened 10 people in Washington state with *E. coli* O157:H7. The lettuce was traced to Salinas Valley, California. In September that same year, California-produced lettuce was implicated in an *E. coli* outbreak that sickened 40 people in five states. Michigan determined that the lettuce was grown in California and processed in Detroit.” However, LGMA critics should be no less cautious than proponents in making bold claims about the effectiveness of the LGMA or other food safety programs on the basis of aggregate data regarding outbreaks. Just as the assertions of LGMA success based on broad generalizations are complicated by aggregate data regarding outbreaks that show no clear trend, so too, assertions of failure based on the continuation of outbreaks following LGMA implementation are also complicated, since even optimal safety programs tolerate residual risk and do not entirely eliminate illness.108

The FDA has attempted to link the use of GAPs to health outcomes in its Regulatory Impact Analysis of the FSMA Produce Safety Rule. The agency asserts that the rule will avert between 331,964 and 362,059 illnesses per year. In calculating the influence of the Produce Safety Rule on the rate of foodborne illness, the agency first estimated the rule’s impact on the risk of contamination. To obtain this estimate, the agency relied on a method called “expert elicitation.” A consulting firm under contract with the FDA asked a panel of six recognized food safety experts to indicate, using a series of scenarios, whether the risk of contamination in a scenario using a particular agricultural practice was less than, equal to, or greater than a baseline scenario without it. The experts were asked to quantify the magnitude of the difference using a scale of 0 to 100, placing the baseline scenario at 50 as a benchmark. For example, the particular agricultural practice might be the use of treated water for irrigation, and an expert might assign a relative risk value to the use of treated water of 39 relative to a baseline scenario set at 50. The consulting firm conducted two such studies, one estimating the effect of interventions on *E. coli* O157:H7 contamination of leafy greens and the other estimating their effect on *Salmonella* contamination in
tomatoes. Using the numerical values from each set of scenarios, the agency calculated a risk ratio for implementing particular food safety interventions, which it expressed as the reduction in the risk of contamination that would be achieved by means of that intervention. For example, based on this method, the agency “infer[ed] that the use of treated water induced by the regulation would mitigate … 32% of the risk of produce contamination from agricultural water.” The agency then similarly calculated the reduction from other interventions of risks from other sources, such as animal intervention, soil amendments, and worker hygiene. By aggregating these estimates for each intervention, the agency calculated that “taken together, this adds up to about a 56.43 percent reduction in risk of contamination.”

Having estimated the rule’s impact on the risk of contamination, the agency then estimated its impact on the risk of foodborne illness. “To translate this percentage reduction in farm contamination to human health outcome, we estimated that a reduced possibility of contamination will result in a corresponding reduction in the expected number of illnesses.” By this, the agency meant that a 56.43 percent reduction in the risk of contamination would mean a 56.43 percent reduction in the rate of foodborne illness.

The agency’s assertion that the Produce Safety Rule will prevent a quantifiable number of foodborne illnesses rests on educated guesses and an unsupported assumption. Expert elicitation produces quantitative risk reduction estimates based on an aggregation of educated ballpark guesses. The precision of the resulting risk reduction percentages obscures the fundamentally impressionistic nature of these estimates and their lack of the kind of scientific rigor typically expected in the life sciences. Moreover, although the agency claims that it “estimated that a reduced possibility of contamination will result in a corresponding reduction in the expected number of illnesses,” it appears—from the lack of any additional explanation—that the agency merely assumes this relationship. Of course, it is not at all counterintuitive to think that reducing the risk of contamination will result in a lower rate of illness, but the agency offers no basis for its assertion of a linear, 1:1 relationship between reduction in the risk of contamination and the rate of illness.
One should be careful not to infer from this scrutiny of the FDA’s Regulatory Impact Analysis any suggestion of agency incompetence or bad faith. The agency operates under a number of competing pressures that help to explain its reliance on expert elicitation and unexplained assumptions. First, Congress mandated that the FDA publish produce safety regulations within two years of the passage of FSMA, regardless of any limitations in the scientific knowledge necessary to support them. When the agency missed the statutory deadline for publishing proposed produce safety regulations along with other rules required by FSMA, it was sued by the Center for Food Safety and ordered by a federal court to publish final produce safety regulations by November 2015. Second, a series of executive orders dating back to the Reagan Administration require federal agencies to provide a regulatory impact analysis that includes a detailed quantitative estimate demonstrating that the expected economic benefits of any proposed rule outweigh its costs. Third, a federal agency faces the prospect of legal challenges that will subject its regulatory analysis to judicial review that may result in the overturning of published regulations if the agency fails to provide sufficient scientific evidence. Thus, although FDA officials undoubtedly appreciate the limits of scientific knowledge regarding the effectiveness of GAPs in reducing foodborne illness, the agency was legally mandated by Congress to publish produce safety regulations, obligated by the President to provide a detailed cost-benefit projection, and under pressure to create an impression of sufficient scientific certainty to satisfy judicial review.111

In the end, the claims asserted in the FDA’s Regulatory Impact Analysis were well justified by administrative necessity. Moreover, one might even believe that, given the limits of current science, the agency provided a reasonable justification for its Produce Safety Rule. Nevertheless, the agency’s projections do little to advance knowledge of how effective GAPs have been in reducing foodborne illness. Frustrated by the dearth of quantitative evidence necessary to evaluate the effectiveness of GAPs, one leading food safety expert in the USDA’s Economic Research Service exaggerated only slightly when she concluded that “produce is a world without data.” Jim Prevor, a leading commentator on the fresh produce industry and author of the widely read online trade publication Perishable Pundit, cautions that there is no data to show that fresh produce subject to one food safety approach is safer than produce
subject to any other approach. Indeed, he concludes, “[w]e have no real data proving that any of these standards make for safer produce.”

When it comes to tort litigation and insurance, some studies have suggested that civil liability has had little or no effect on encouraging food companies to improve their food safety practices. Based on a review of jury verdicts and settlements in foodborne illness tort claims reported in legal databases between 1988 and 1997, USDA economists Jean Buzby and Paul Frenzen concluded that tort litigation provides companies “weak” incentives to improve their food safety practices. Buzby and Frenzen estimated that fewer than 0.01% of all foodborne illness cases during this period gave rise to litigation and found that only a fraction of lawsuits resulted in companies paying any compensation. Buzby and Frenzen explained that most victims never recognize food as the source of their illness, fail to obtain medical tests that identify the responsible pathogen, or do not save samples of the contaminated food—all of which are necessary to link the victim’s illness to a particular company that sold the contaminated food. Moreover, Buzby and Frenzen found that companies paid compensation in 56% of the lawsuits in their sample, and that “the median compensation was only $2,000 before legal fees.” They explained that “most foodborne illnesses are mild and short-lived and do not incur medical and other costs high enough to make litigation worthwhile for plaintiffs,” and that the amount of compensation paid, even in more serious cases, provided little incentive to plaintiffs’ attorneys to pursue litigation.

Buzby and Frenzen’s analysis has several important limitations. Dennis Stearns, an attorney who works with Bill Marler, has suggested that Buzby and Frenzen’s sample of reported jury verdicts and settlements between 1988 and 1999 may not be representative of litigation in more recent years. In 2009, Stearns wrote that “the vast majority of legitimate food-injury claims never go to trial and are privately settled. In the 10-year history of Marler Clark, only one of the firm’s cases ever went through trial to verdict; all others settled.” Marler adds that companies with well-known brands typically settle claims before they are even filed to stay out of the news.

Buzby and Frenzen themselves note that the influence of litigation on food companies is “slightly stronger in outbreak situations and markets where foodborne illness can be more easily traced to
individual firms.” They also suggest that “indirect incentives for firms may be important and deserve more research. For example, firms may be influenced by costly settlements and decisions against other firms in the same industry.” The impact of tort claims arising out of outbreaks extends beyond what Buzby and Frenzen suggest in these qualifications of their analysis.¹¹⁵

Buzby and Frenzen’s focus on the economic costs of litigation outcomes—jury verdicts and settlements—overlooks the framing effects of the litigation process—filing, pleading, discovery, and negotiation—which has, at crucial junctures in the evolution of food safety, generated and sustained media coverage that recast the issue of bacterial contamination from a natural hazard to a product of human error, and thereby focused attention on industry food safety practices. The impact of litigation following the Jack-in-the-Box beef outbreak in 1993 (discussed at length in the previous chapter) or the Dole baby spinach outbreak in 2006 cannot be accurately assessed merely in terms of the economic costs of the final settlements. In both instances, litigation and the news coverage that accompanied it heightened the reputational concerns of company executives throughout an entire food industry sector, focused the attention of government regulators on those sectors, stoked consumer demands for advances in food safety, and mobilized consumer advocates to lobby for policy reforms.¹¹⁶

According to one study, the reputational concerns stirred up by litigation influence food company behavior more than the economic impact of a jury verdict or settlement: “Word-of-mouth notoriety is far more devastating in its cumulative effect than the fleeting shadow of a single publicized judgment awarded to an unknown plaintiff.” As Buzby and Frenzen put it, “[i]t is primarily the business disruption and negative publicity of the catastrophic foodborne illness or outbreaks that cost firms money[,] so it is these extraordinary, nonrecurrent illnesses or outbreaks that have the potential to substantively shape corporate behavior. In the rare instances where foodborne disease outbreaks are linked to particular firms, the impact on those firms can be large. For example, … Jack in the Box Inc. lost an estimated $160 million in the first 18 months after the 1993 E. coli O157:H7 outbreak.” Here again, Buzby and Frenzen understate the impact of the Jack-in-the-Box litigation—which not only influenced Jack-in-the-Box, but also generated pressure for reform throughout the entire beef industry.¹¹⁷
Marler concedes that the volume of litigation compared to the rate of foodborne illness is very small. Agreeing with Buzby and Frenzen, he observes that “the vast majority of outbreaks are never identified. People have no idea what poisoned them, and so they don’t see anybody to hold accountable.” Tort liability does not provide a straightforward “check” on the food industry, according to Marler. Instead, the litigation process serves as “a catalyst to professionals in industry, health officials, and consumer advocates.” Of course, framing, reputational, agenda-setting, and mobilization impacts are not subject to measurement in the way that economic costs are—but any comprehensive analysis of tort litigation’s impact on food safety must somehow take them into account.\textsuperscript{118}

\textit{Comparing the Different Approaches based on Process Values}

Attempts to assess different approaches to food safety sometimes focus on process rather than outcomes. This type of assessment—which scholars refer to as “comparative institutional analysis”—compares the relative strengths and weaknesses of different approaches in terms of process values, such as, for example, stakeholder participation. From a process point of view, one might favor an approach to food safety characterized by broader and more meaningful stakeholder participation over an approach characterized by relatively narrower and less meaningful stakeholder participation, on the theory that any resulting standards will be the product of a wider spectrum of expertise and experience, and that they will engender greater respect among the stakeholders to whom they apply. Thus, consumer advocates have argued that government regulations are preferable to industry guidance because the government’s notice-and-comment process is characterized by more robust stakeholder participation than the processes used by industry to make private standards. In addition to stakeholder participation, other process values that may be used to assess different food safety approaches include impartiality, transparency, accountability, compliance, administrative efficiency, and the capacity to generate feedback and learning.\textsuperscript{119}

Comparative institutional analysis is complicated by a number of factors. To begin with, in the absence of quantitative baselines and metrics, comparisons between different regulatory approaches on the basis of process values is an impressionistic exercise. For example, comparisons between the
robustness of stakeholder participation in notice-and-comment rulemaking and in standard setting by industry association technical committees are matters of interpretation not subject to well-defined standards of proof.

In addition, pursuit of one process value may come at the expense of another. For example, more robust stakeholder participation may reduce administrative efficiency and the agility of regulatory institutions to revise standards based on feedback and learning. Ensuring that decisions are made on the basis of impartial expertise may require insulating decision makers from the influence of stakeholders, thereby making them less publicly accountable. Comparative institutional analysis provides no basis for weighing competing process values when tension between them requires unavoidable tradeoffs.

Moreover, different regulatory approaches are not necessarily exclusive. They frequently coexist and may, in some instances, complement each other. For example, private food safety audits and marketing agreements may promote compliance with government regulations. As the FDA has said, “[t]o the extent that certification schemes or food safety programs are consistent with the produce safety regulation, then compliance with those schemes or programs could be relevant to compliance with the requirements of [the regulation].” This type of complementarity suggests that comparative institutional analysis should not analyze the process advantages and disadvantages of any one approach in isolation, but rather evaluate different combinations of approaches.120

To complicate matters further, some aspects of food safety regulation involve collaboration between more than one institution. For example, the development of GAPs standards has been characterized by the extensive involvement of government agency officials in private standard setting groups and heavy reliance on private standards as the basis for government guidance and regulation. Food safety norms are the product of ongoing conversation among experts in industry, government, and academia that takes place in a variety of institutional settings. Implementation is similarly characterized by collaboration between institutions. For example, the California LGMA relies on government auditors to certify compliance with private industry standards. The hybrid nature of many food safety programs makes it harder for comparative institutional analysis to rely on broad categorical generalizations about the process
advantages and disadvantages of different types of institutions—for example, that government agencies
tend to be more transparent, impartial, participatory, and publicly accountable than industry organizations,
and that industry organizations are typically more efficient and quicker to incorporate feedback and
learning. Hybridization blurs standard institutional taxonomies—such as the distinction between public
regulation and private ordering—that simplify comparative institutional analysis.¹²¹

Finally, beyond complementarity and collaboration, different institutions involved in food safety
regulation exhibit what Sociologists Paul DiMaggio and Walter Powell have called institutional
isomorphism—a process in which organizations copy principles, practices, and structural features of other
organizations with which they are in competition for political power and institutional legitimacy. One
example of institutional isomorphism is the evolution of private standard setting processes that
increasingly seek to emulate government notice-and-comment rulemaking. Having endured criticism that
the original LGMA leafy greens metrics were developed in unannounced, private meetings by a small,
self-selected group of executives from large processing companies, the Western Growers Association
(WGA) has since developed a process for developing new and revised standards that provides public
notice at every stage of the process, encourages broad stakeholder input, responds to comments, provides
written justification for decisions, subjects final proposals to open public hearings with a written record
before the LGMA’s Technical Committee, and includes two post-hearing reviews by the LGMA Board
and the California Secretary of Agriculture before a change is approved. The WGA and the companies
that comprise it have sought to bolster the legitimacy and influence of the LGMA metrics by copying
these elements of government agency rulemaking associated with transparency, participation, and
accountability.¹²²

In another example of isomorphism, government agencies have increasingly adopted elements of
industry supply chain management, such as reliance on voluntary guidance and outsourcing inspection.
Since the late 1990s, the FDA has relied heavily on voluntary guidance modeled on guidelines issued by
trade associations like the International Fresh Cut Produce Association and the Western Growers
Association, and the United Fresh Fruit and Vegetable Association. Reliance on voluntary guidance rather
than enforcement actions helped the FDA to boost its legitimacy among growers and handlers by building an image as a flexible partner in food safety rather than a government policeman. More recently, FSMA contemplates that the FDA will rely extensively on private auditors paid for by importers and growers who are subject to new import and produce safety regulations. Outsourcing monitoring in this fashion is associated with greater efficiency than trying to maintain a sufficiently large in-house inspection force. Outsourcing thus helps the agency avoid the common criticism that government regulation is inefficient compared to private alternatives.

Institutional isomorphism further erodes categorical generalizations about comparative institutional virtues and vices—such as the inefficiency of government regulation or the lack of transparency of industry standard setting. Differences between alternative approaches to food safety regulation do remain, but capturing them requires leaving aside increasingly inaccurate generalizations in favor of more detailed analysis.¹²³

In the end, comparative institutional analysis helps clarify process values and highlights their role in regulation. Process concerns have driven the evolution of the different approaches to fresh produce food safety in ways that their proponents believe make them more effective in reducing the risk of foodborne illness. However, one should keep in mind that—because of lack of baselines and metrics, incommensurability among various tradeoffs between process values, complementarity among different approaches, collaborations that cross institutional boundaries, and institutional isomorphism—comparative institutional analysis yields limited insight into the preferability of one approach over another.

*Harvesting Insights*

Donella Meadows, a pioneering scholar of systems theory, defines a system as “an interconnected set of elements that is coherently organized in a way that achieves something.” A system achieves its purpose through feedback. For example, the air conditioning system of a house is composed of an interconnected set of elements—air conditioning unit, ducts, thermostat—which are organized in such a way as to
maintain a constant temperature in the house. The thermostat measures the current temperature of the house and provides feedback to the air conditioning unit, which causes the unit to continue or cease producing cool air conveyed throughout the house by the ducts.\footnote{124}

A system may itself be composed of subsystems. The air conditioning unit—composed of a compressor, coils, and a fan—is a subsystem of the air conditioning system of the house. So, too, are the ducts and the thermostat, which can similarly be broken down into the interconnected elements that comprise them. If one “zooms in,” each of these subsystems can be further analyzed into subsystems of subsystems, such as the electrical, coil, and air-circulation systems within the air conditioner. If one “zooms out,” the air conditioning system of the house can be viewed as a subsystem within the larger electrical system of the region, which is a subsystem of the national electrical grid, which is a subsystem of the global energy system. Systems theory refers to this nested structure of systems and subsystems as “hierarchical” organization. In analyzing such a system, one can “zoom in” or “zoom out” to examine the workings of the system at different “levels” of organization.\footnote{125}

Systems theory can be used to describe food safety regulation. For example, a private third-party food safety audit is a system involving relationships between a buyer, a supplier, and an auditor. The auditor provides feedback to the buyer and the supplier concerning the food safety practices of the supplier. Based on this feedback, the buyer will decide whether to purchase goods from the supplier. The feedback may also encourage the supplier to change its food safety practices. At the same time, the buyer and the supplier provide feedback to the auditor concerning their satisfaction with the audit, which may lead the auditor to modify its auditing practices in ways that balance rigor and cost.

Food safety regulation is a hierarchically organized system. Audits are subsystems of supply chain management systems, which involve networks of multiple suppliers, buyers, and auditors. Within these networks, an individual participant may play different roles, depending upon the nature of a particular transaction (e.g. a handler is a buyer vis-à-vis a grower but a supplier vis-à-vis a retailer). Supply chain management systems exist for different commodities (e.g. lettuce, tomatoes, onions), which are part of larger sectors (e.g. fresh produce, meat, dairy). Supply chain management systems are also nested
geographically (e.g. local, regional, national, and global). In addition, supply chain management is a subsystem of industry association efforts to encourage uniform food safety practices by developing guidance and sponsoring the creation of food safety schemes. The various standards and schemes are subsystems of GFSI’s efforts to establish universally-accepted benchmarks. This analysis becomes more complicated when one takes into account the many additional participants in these systems (e.g. trainers, consultants, accreditors), and the fact that companies may include food safety within supply chain management systems that are concerned with additional product characteristics (e.g. quality, cost, inventory).

A complete description of the food safety system would have to include similar analyses of the nested systems of government regulation and tort liability, as well as the networks of professionals (each with their own sub-networks in industry, government, academia, and advocacy organizations) that create interconnections within and among the different parts of the system. Hybrid approaches (e.g. USDA fee-for-service audits, marketing agreements, FSMA reliance on private audits) blur institutional distinctions and further complicate the analysis.126

Throughout the system, the actions different agents (e.g. individuals, groups, institutions) change the context for other agents and influence their actions. For example, the publication of guidance by an industry association typically defuses pressure on government agencies to develop new regulation. When plaintiffs sue food companies, the resulting liability exposure creates a demand for liability insurance which, in turn, finances additional litigation. Advances in tracing technology developed by scientists in academia or public health agencies illuminate the connections between specific food safety practices and foodborne illness, which informs the efforts of government regulators, supply chain managers, plaintiffs’ attorneys, and insurance underwriters. Feedback prompts learning and adaptation among the participants, enabling the system to evolve over time.

Attempting to analyze the vast network of changing relationships and elaborate feedback loops that comprise such a complex system can be overwhelming. “Once you start listing the elements of a system, there is almost no end to the process,” warns Meadows. “You can divide elements into sub-elements and
then sub-sub-elements. Pretty soon you lose sight of the system. As the saying goes, you can’t see the forest for the trees.” Beyond the multitude of elements, the evolving web of interactions and multifarious and multidirectional paths of influence at different levels of organization makes it difficult to describe complex systems or analyze how they function. Complexity theory, a branch of systems theory, seeks out recurring structural and behavioral patterns within complex systems that provide insights into how they work and how one might “steer” them to work more effectively. Examples of such patterns can be found in food safety efforts in the leafy greens sector.127

The 2006 Dole baby spinach outbreak illustrates a recurring pattern of reputational interdependence. The contamination of spinach plants in the field and the spread of that contamination during processing damaged the reputation of the entire spinach industry. Even producers with rigorous food safety practices suffered dramatic losses as the market for spinach collapsed. “When one company has an issue, we all suffer,” explains Drew McDonald, who was at Taylor Farms at the time. “If there’s an outbreak and it’s spinach, the consumer doesn’t hear “spinach from so-and-so’s farm.” The consumer hears “spinach,” and they stop buying spinach. And so, you’re only as good as your neighbor,” says Bob Whitaker who, at the time, was at NewStar Fresh Produce. Beyond spinach, “when there’s a foodborne illness outbreak, it not only affects the responsible company, but everybody in that category. So if someone makes a mistake, and there is a foodborne illness associated with a particular commodity, everybody in the at commodity suffers from decreased sales,” adds Jim Gorny.128

Reputational interdependence occurs in other places within the food safety system. For example, private food safety auditors express the same sense of being collectively discredited following outbreaks associated with the failure of a single audit firm. At a higher level of organization within the system, one sees a similar reputational interdependence between an entire food industry sector and the government agency responsible for regulating it. As the spinach industry collapsed in the fall of 2006, the FDA faced allegations by consumer advocacy groups that its food safety efforts were ineffective and failed to protect the public, and agency officials faced stinging questions about the agency’s competence in Senate hearings.129
Reputation is, of course, a powerful motivator. The profitability of a food company depends on its ability to build and protect the reputation of its products. Similarly, the power of a government agency to influence industry behavior and inspire public confidence depends on its reputation for effectiveness, integrity, expertise, and fairness. When the failure of one agent can damage the reputation of others—when they are what regulatory scholar Joseph Rees calls “hostages of each other”—they frequently band together to repair damage that has already occurred and prevent additional damage in the future. Rivals become collaborators; competition gives way to cooperation. Industry insiders credit the industrywide shock of the 2006 baby spinach outbreak as the impetus for the LGMA. The WGA’s leading role in developing and sustaining the LGMA illustrates how trade associations institutionalize cooperation among industry competitors. Government agencies like the California Department of Food and Agriculture and the FDA have been heavily involved in and highly supportive of leafy green industry initiatives such as the LGMA, in no small measure because the agencies’ reputations can rise or fall with the industry’s.\textsuperscript{130}

A second recurring pattern within the complex regulatory system of food safety is reliance on regulatory intermediaries. Regulatory scholars Kenneth Abbott, David Levi-Faur, and Duncan Snidal, explain that regulators seeking to influence the behavior of targets of regulation often rely on what they call “regulatory intermediaries.” According to Abbott et al., “[t]he principle reason for regulators to incorporate intermediaries into the regulatory process is that intermediaries possess capacities relevant to regulation that regulators themselves lack, or that intermediaries can provide more effectively or at lower cost.” Regulatory intermediaries add “operational capacity” to regulatory efforts by, for example, gathering information, facilitating implementation, monitoring the behavior of targets, enforcing standards, and channeling feedback that leads to learning and improvement over time. Regulatory intermediaries also provide expertise to regulators, and their independence may boost the legitimacy of the regulatory process.\textsuperscript{131}

Relationships throughout the food safety system exhibit this regulator-intermediary-target (R-I-T) structure. For example, within the context of government regulation, administrative agencies serve as
intermediaries between legislatures and food companies when the agencies create, implement, and enforce regulations pursuant to general statutory mandates to regulate companies: R (legislature) → I (agency) → T (food company). As an intermediary between Congress and industry, the FDA provides operational capacity through administrative rulemaking, inspection, implementation, monitoring, enforcement, and reporting; lends expertise in areas such as microbiology, epidemiology, and forensics; and enhances the legitimacy of regulation by distancing it from legislative politics.132

Within the context of industry supply chain management, retail stores set food safety specifications for their suppliers and rely on private food safety auditors to verify compliance: R (retailer) → I (auditor) → T (supplier). Private auditors serving as intermediaries between retailers and their suppliers make supply chain management more efficient. Maintaining an in-house staff of food safety inspectors with expertise in many areas of food production and paying for their travel to visit widely dispersed suppliers would significantly increase retailers’ production costs. Consequently, companies rely on private third-party auditors, who can more efficiently perform audits because they typically have many clients in a single geographical area and possess specialized expertise in particular food production sectors and inspection techniques.

Within the context of civil liability, insurers translate the threat of litigation by plaintiffs’ attorneys into insurance incentives—using risk selection, pricing, contract design, and loss prevention—that encourage food companies to improve their food safety practices: R (plaintiffs’ attorney) → I (insurance underwriter) → T (food company). In contrast to the first two examples, this third example does not involve a conscious decision by the regulator (the plaintiffs’ attorney) to rely on the intermediary (the insurance company), nor does the regulator instruct, direct, or oversee the intermediary. Moreover, the attorney’s role as a regulator is a byproduct of efforts to obtain compensation for his or her client. Nevertheless, insurers enhance the regulatory impact of private lawsuits in ways that conform to the pattern of reliance on regulatory intermediaries.

R-I-T relationships cross the boundaries between these three subsystems of government regulation, industry supply chain management, and civil liability. For example, industry supply chain managers may
rely on government inspectors to audit their suppliers, as illustrated by LGMA audits. Conversely, government agencies may rely on private auditors to assess regulatory compliance, as contemplated in FSMA.

Moreover, R-I-T relationships also occur at different levels of organization. For example, zooming in to the level of firms, one finds that insurance underwriters rely on private auditors and in-house loss control experts to help select and price risks, design contract terms, and advise food company clients about reducing risk. Zooming out to the level of sectors, one sees that the liability insurance system as a whole serves as a regulatory intermediary that enhances food industry compliance with government regulation. These examples illustrate that intermediaries can be individuals, institutions, or entire sectors of activity.

R-I-T relationships may combine in different ways to enhance regulatory efforts. Multiple R-I-T relationships may work “in parallel” to reinforce each other. For example, leafy greens handlers are subject to FDA regulations enforced by government inspectors, retail specifications verified by auditors, and liability exposure that is translated into risk reduction incentives by insurance companies, as illustrated by Figure 4.2.

**Figure 4.2**

R₁ (FDA) → I₁ (government inspector)
R₂ (retailer) → I₂ (auditor) → T (handler)
R₃ (attorney) → I₃ (insurance underwriter)

R-I-T relationships may also be nested in ways that enhance the effectiveness of reliance on intermediaries. For example, buyers who rely on auditors to audit their suppliers may rely on food safety schemes to oversee the auditors. Food safety schemes typically include detailed standards for auditors, including principles, policies, and practices to maintain consistently high audit quality and address any conflicts of interest. Schemes license auditors to certify compliance with the scheme on the condition that
the auditors obtain accreditation to ensure that the auditor is in compliance with the scheme’s standards for auditors. Thus, the schemes rely on accreditors to oversee the auditors. The R-I-T relationship between the scheme, the accreditor, and the auditor is nested within the R-I-T relationship between the buyer, the auditor, and the supplier: R (buyer) → I [R (scheme) → I (accreditor) → T (auditor)] → T (supplier).

As this example illustrates, relationships between regulators and the intermediaries on whom they rely are subject to agency problems. In this case, buyers worry that auditors may reduce the rigor of audits because suppliers are paying the auditors. To address such agency problems, regulators rely on additional intermediaries. Here, buyers rely on food safety schemes to impose licensing standards on auditors that will counteract any incentive to reduce the rigor of audits. Note that the initial intermediary (the auditor) becomes a target of regulation. The additional regulator-intermediary relationship created between the buyer and the scheme to oversee the auditor is also subject to agency problems which may be addressed by reliance on additional intermediaries. For example, buyers rely on GFSI to provide benchmarks and certify the reliability of schemes. Similarly, to address the agency problems between schemes and auditors, schemes rely on accreditors.

The structure of the relationships among intermediaries also varies. In order to address the agency problems that arise with reliance on accreditors, scheme owners require that accreditors be accredited by the International Accreditation Forum (IAF). The IAF accredits accreditors through a system of peer review, as illustrated in Figure 4.3.
There are several reasons to believe that additional intermediaries (in this example, food safety schemes and accreditors) reduce agency problems between regulators (buyers) and the initial intermediaries (auditors) on whom they rely. First, it is marginally easier for regulators to monitor the performance and reputation of a relatively small number of additional intermediaries. The capacity of an intermediary to oversee multiple targets gives intermediary oversight a pyramidal structure, in which additional intermediaries (food safety schemes and accreditors) are fewer in number than the relatively larger number of intermediaries (auditors) they oversee. Second, regulators can employ multiple additional intermediaries to provide simultaneous oversight of the same intermediary, as buyers sometimes do by relying on both food safety scheme owners to license auditors and accreditors to accredit them. The assumption here is that multiple sources of oversight are more reliable than a single source. Moreover, if the additional intermediaries operate independently, as do food safety schemes and accreditors in overseeing auditors, regulators are less vulnerable to an oversight failure by one additional intermediary. Third, additional intermediaries can oversee one another, creating a web, or network, of oversight, as is the case with IAF peer review. Such a web of oversight may be less vulnerable to failures by a single overseer than a strictly sequential chain of oversight.\textsuperscript{133}

The advantages that intermediaries offer to regulators, and the need to employ additional intermediaries to address agency problems, leads to the proliferation of R-I-T relationships throughout the
complex system of food safety regulation. The ongoing generation of R-I-T relationships, in various configurations and combinations, and at various levels of organization, in response to regulatory challenges illustrates the phenomenon of “self-organization,” which is characteristic of complex systems. Such spontaneous adaptation drives the evolution of complex systems over time.\(^{134}\)

A third recurring pattern within the complex regulatory system of food safety is \textit{rule emergence}. In a complex regulatory system, some rules are not issued by an identifiable individual or institution. Instead they emerge out of the interactions of many actors and institutions linked by multiple networks within and between subsystems. GAPs provide a good example. Although GAPs originated as a set of recommendations by a panel of experts assembled by two industry associations, they quickly evolved into a constellation of standards embedded in guidance issued by trade groups and government agencies, buyer specifications, audit criteria, best practices among growers, academic and university extension publications, marketing agreement metrics, government regulations, standards of care in tort litigation, and liability and recall insurance underwriting guidelines. Some GAPs are the product of formal deliberation and are recorded in carefully drafted documents. Others arise out of experience on the job and are shared by word of mouth.\(^{135}\)

These multiple sources of GAPs are interdependent. For example, underwriting guidelines derive from a variety of sources, including standards of care in tort litigation, government regulations and guidance, food industry best practices articulated by trade associations, food safety scheme criteria, and the recommendations of academic experts and independent consultants. Each of these inputs functions in other parts of the food safety system as a rule. The influence of these rules on the underwriting guidelines applied by insurers is represented in figure 4.4.
These underwriting guidelines, in turn, influence the rules that influence them. For example, industry associations, when establishing best practices, are mindful of underwriting guidelines, as well as government regulations and guidance, standards of care in tort litigation, expert recommendations, and scheme criteria. A similar diagram for industry best practices would depict industry best practices in the center surrounded by the rules that influence them. The same analysis applies to all of the rules in the system ($r_1 - r_6$), each of which could be depicted in a diagram with that one in the center and the others arrayed around it, as illustrated in Figure 4.5.

The relationship between these different rules and the agents who apply them is more than just a collection of iterative cycles of feedback and learning. It is not merely the case that, for example,
industry best practices inform underwriting guidelines, which, as they are refined over time based on lessons from claims management, in turn, influence industry best practices. Rather, the relationship between these rules is interdependent in a constitutive sense. Although not identical in all respects, they draw heavily upon one another for their content. For example, insurance underwriting guidelines are drawn directly—sometimes verbatim—from government regulations and guidance, standards of care in tort litigation, food safety schemes, expert recommendations, and industry practices. The same is true for these other rules vis-à-vis each other. Rules thus emerge out of a pool of experts working in different institutional settings, in dialogue with one another, facilitated by network connections. Within this network of interdependence, rule making has no beginning or end, and no one party plays a predominant role as a rule-maker, as represented in figure 4.6.

**Figure 4.6**

![Network Diagram](image)

This representation is an oversimplification, as it depicts a simple network; whereas, in the case of food safety governance, rule emergence occurs within a complex network—a network of networks, represented in figure 4.7.
Thus, rulemaking in the food safety system does not reside in rule makers, insofar as that term denotes a discrete individual or institutional agent from which rules issue. Instead, it appears that rules emerge out of ongoing interactions within a complex network.

To obtain a better grasp of the concept of rule emergence, it may be helpful to consider two familiar examples. Within a system of market exchange, prices emerge. No rule maker or rulemaking body sets prices. Rather, they emerge from ongoing interactions among buyers and sellers. Similarly, the rules of grammar emerge from ongoing interactions among speakers of a language, teachers of the language, and professional linguists who analyze the language. The rules of grammar are not determined solely by informal conversation or formal language instruction or scholarly treatises. Instead, they emerge from interactions among members of each of these groups and between members of different groups (e.g. when linguists study common usage or when speakers take formal classes), and they evolve through ongoing feedback and learning.136

This account of rule emergence has implications for analyzing authority within a complex regulatory system. Within a network conception of rulemaking, the authority of rules cannot be easily anchored in
the authority of a discrete rule maker or even an easily identifiable rule of recognition. It may be the case that the authority of rules that emerge within complex systems of regulation derives not from the source of the rule, but instead accretes over time based on growing acceptance of the rules by participants in the network.¹³⁷

A network account of rulemaking also challenges the tendency of many regulatory scholars to view government regulation through legislation and notice-and-comment rulemaking as a benchmark—in terms of participation, transparency, and accountability—against which to evaluate the legitimacy of private alternatives. A network perspective does not privilege government regulation or view it as a default or first-best option—it is merely one of a number of networks within a complex network, the legitimacy of which must be assessed in comparison with other forms of regulation within the system. Moreover, a network perspective reveals ways in which the legitimacy of one rule depends upon that of another. For example, the incorporation—formal or informal—of industry standards into government regulations and guidance gives government rules greater legitimacy in the eyes of regulated entities. Similarly, incorporating private industry standards into government regulations and guidance validates the private standards and makes them more legitimate to consumers.¹³⁸

Finally, a network conception of rulemaking reveals important structural features of complex regulatory systems identified by network theory. One feature is network density—the extent of interconnection among participants in the network, defined by the proportion of links between individuals to the total number of possible links within the network. Density may be relevant to a number of issues in complex regulatory systems. For example, higher density may improve the quality or pace of feedback and learning, making the system more responsive and thereby, perhaps, more effective and legitimate. Higher density may also increase transparency, enhance oversight, and facilitate the diffusion of industrial morality. Many commentators consider industrial morality—a shared sense of mission, frequently referred to in food safety regulation as a “culture of food safety”—to be a key factor in effective risk management.¹³⁹
Another structural feature of complex regulatory systems is the importance of relationships that bridge the dense networks that define subsystems. Relationships within close-knit social or professional networks tend to be characterized by a common pool of information, shared priorities, and a common outlook. Relationships with acquaintances outside of these dense networks expose the individuals in the relationships to new information and ideas that they then can introduce into their close-knit networks.

Sociologist Mark Granovetter explains that these “weak” ties are “much more likely than strong ones to play the role of transmitting unique and nonredundant information across otherwise largely disconnected segments of social networks.” He calls this “the strength of weak ties.” Such weak ties expand the diffusion of feedback and learning, and they are essential to the emergence of rules within complex regulatory systems.

Weak ties are forged throughout the food safety system at different levels of organization and by many different means. Industry associations facilitate weak ties between food safety managers within different companies. Interagency task forces forge weak ties between officials in different government agencies. Academic conferences allow the diffusion of research findings among researchers working in different universities. Professional societies link food safety professionals working in government, industry, academia, and insurance. Other examples include government and industry funding for academic research, reliance by food companies and insurance underwriters on outside consultants from industry and academia, study groups convened by industry and government to issue reports on specific issues, and the movement of professionals between jobs in industry, government, and academia. At a more general level of organization, industry associations, like the WGA, serve as a bridge not only between member companies, but also between industry, government, and academia. “I consider us to be kind of a liaison between the regulatory community and the industry,” explains Hank Giclas. “We try to help the industry understand the government’s policy goals, and we try to help regulators understand the practicalities of what can and can’t be done in the field and some of the things that actually are already occurring in the field. We’ve built up strong collaborative working relationships with FDA, the EPA, with a lot of the state agencies, the academic circle, and of course with the industry itself.” Although the
diffusion of information and ideas throughout the system advances food safety, weak ties are not always beneficial—for example when they facilitate ties between regulators and regulated entities that increase opportunities for capture and corruption.141

A third structural feature of complex regulatory systems made visible by a network approach is redundancy. For example, multiple regulators apply versions of the same rules to the same target of regulation. Thus, growers are subject to multiple private audits required by buyers, government regulators, and insurance underwriters. Network theory suggests that such redundancy gives a system greater resilience—the ability of the system to continue to function despite a breakdown or failure in one part of the system.142

The interconnections within a system often produce what Meadows calls leverage points: “places in the system where a small change could lead to a large shift in behavior.” Within the complex system of food safety regulation, there is perhaps no leverage point more significant than the technology and techniques available for identifying foodborne illness and tracing it back to a specific food safety failure. The development of foodborne illness tracing is the driver for the system’s capacity for feedback and learning. The next chapter traces that history and its implications for the evolution of the food safety system.
NOTES

1 McDonald interview 10; CNN World, Sept. 14, 2006; FDA Warning Letter to Consumers, September 14, 2006; FDA Warning Letter to Consumers, Sept 15 2006; Cuite, Public Response 3; Senate Hearings on Spinach Outbreak, November 15, 2006, 8; account of events also in Calvin, Outbreak Linked to Spinach
2 Gombas interview 5; Cuite 18; McDonald interview 11; Whitaker interview 18; see also statement of Dan Verdelli, Senate Hearings on Spinach Outbreak 78
3 Brackett interview 2; FDA Warning Letter to Consumers, Sept. 15 2006; FDA Warning Letter to Consumers, Sept. 21 2006; FDA Warning Letter to Consumers, Sept. 29 2006; California Spinach Final Report 2007 24; quote from Food Industry Center, Natural Selection 18; see also Senate Hearings on Spinach 40, 46; fears of bioterrorism persisted: Food Industry Center 28
4 For detailed timeline of outbreak, see Food Industry Center 15-19 and Marler 2006 Dole Spinach E. coli O157:H7 Outbreak
5 Whitaker interview 18-19; Gombas interview 5; see also Food Industry Center 20; Senate Hearing on Spinach 78; Calvin Outbreak Linked
6 Shekhar, Produce Exceptionalism 279, see also Endres, Integrating Stakeholder Roles 51 citing GAO, Food Safety Improvements 1 for $100m losses; Senate Hearings on Spinach 45-46; Calvin, The Economics of Food Safety in Fan et al. MICROBIAL SAFETY 412-415; Fan et al., MICROBIAL SAFETY 108 (extent of losses, $75 m)
7 FDA Warning Letter to Consumers, Sept 29, 2006; FDA Warning Letter, Feb. 5, 2004; FDA Warning Letter, Nov. 4, 2005; see also Marler, E coli and Lettuce
8 FDA Warning Letter, Nov. 4, 2005
9 CDC, Multistate Outbreak of E. coli Spinach 1-2; note that Marler put the number of deaths at 5, Food Industry Center 16; Endres 51 citing GAO Food Safety Improvements 1 for # cases
10 California Food Emergency Response Team, Investigation of and Escherichia coli Outbreak 3-4; Gombas interview 7; Food Industry Center 20-23; Daniels, Nationwide Produce Outbreak 4; Senate Hearings 28, 33, 35; Fan et al. 22
11 Gombas interview 4-5; for more detail on rise of foodborne illness in fresh produce in decade prior to 2006 outbreak, see Fan et al chs. 1, 5, 20, and Calvin, Outbreak Linked
12 Gombas interview 4-5; Schwartz interview 2
13 Horsfall interview 14.
14 Gombas interview 1; Schwartz interview 6; Smith interview 3; Senate Hearings 30, 36-37, 92; Schmidt, Tainted Spinach; Endres 54; Costa, Current Issues in Produce Safety The Packinghouse Process Water; CPS, Key Learnings 9; Food Industry Center, Natural 7; Nestle, SAFE FOOD loc 2846 (irradiation); Fan, Irradiation of Fresh Fruits; Booth & Brown, Eating Dangerously, loc 2282 (irradiation); Fan et al. 109, 421 (prevention key), 45 (many sources of contamination in the field)
15 Endres, Integrating 53-54; Cain, Salads and Safety 3; Fan et al. ch 3
16 Gombas 2, Congressional Research Service, FDA Authority to Regulate On-Farm; FDA Guide to Produce Farm Investigations 3; CFR Title 21 Sec 110.19; Shekhar 269, 273; National Academies, An Evaluation of the Salmonella Problem 257-258
17 FDA Guide to Produce Farm Investigations 2; Whitaker interview 2, Smith interview 2; Suslow interview 4;
18 Kohinke, Reeling In 499; FDA Guide to Minimize Microbial Food Safety Hazards 3-4; Smith interview 3; Whitaker interview 1-2; Gombas interview 2-3; Suslow interview 2
19 IFPA-WGA, Voluntary Food Safety Guidelines, iv-v; In the summer of 1995, the National Advisory Committee for Microbiological Criteria for Food had formed a Fresh Produce Working Group. Concurrently, United Fresh convened a Produce Microbiology Committee to study microbiological food safety. Eventually, this committee developed into the United Fresh Food Safety and Technology Council. Prior to 1995, United Fresh had a Science and Technology Committee focused on agricultural inputs and EPA regulations. Stenzel, email 11/15/16
20 IFPA-WGA, Voluntary Food Safety Guidelines; United Fresh, Guidance to Minimize; United Fresh, Food Safety Auditing Guidelines; Smith email on Cornell pamphlet, Cornell, Prevention of Foodborne Illness. for a more detailed definition of GAs, see Fan et al 108-9
21 IFPA-WGA 1-2 (list numbering removed)
22 IFPA-WGA ii, 2-3
23 IFPA-WGA ii-iii
Agricultural Practices

Interview 5

Get cites for Canada closure & Taco Bell outbreak

Albersmeier, 303; $500

Pronk, 53

Interview 9; Horsfall interview 1; Federal Register, FSMA Proposed Produce Safety Rule 3513 (IFPA Food Safety Guidelines)

Interview 7, Gombas interview 4; IFT, Preventive Control Measures ch 5 sec 3

FDA, Warning Letter 2004 2; FDA, 2004 Action Plan 3; FDA, Warning Letter, Nov. 5, 2005; Smith interview 8

Giclas interview 4

Commodity Specific Food Safety Guidelines iv

Commodity Specific Food Safety Guidelines 4; Gombas interview 8

Brackett interview 3; Senate Hearings, Nov 15 2006 10; Smith interview 5; Calvin, Outbreak Linked 5; Fed Reg FSMA Proposed Produce Safety Rule 3512

Motivated by fear of outbreak/liability: Zagory 3, Chestnut 2

Prince interview 2; Yiannis interview 2; Wilson interview 1; McDonald interview 11

McLaughlin, Produce Industry Procurement 6-7; Hansen interview 7; Thesmar interview 3; Acheson 12/15/14 interview 2; Stier interview 5; Chestnut interview 1; McLaughlin, Produce Industry Procurement 7; Prevor 8-13-13 interview 2

Prevor 8-13-13 interview 2-3; McLaughlin, 7-8; Theno 9/5/14

Costa 4, Davis interview 6; Theno 9/5/14 interview 8-9; Prince 8-6-13 interview 3; Prevor email; Chestnut interview 1; Hensen & Northern, Economic Determinants; Fulponi, Private Standards 5

Wilson 8-15-13 interview 2 Davis interview 7; Prevor email; Chestnut interview 1

For cites, see Lytton & McAllister, Oversight in Private Food Safety Auditing 290-291; FDA, Preliminary Regulatory Impact FSVP (estimate of 568); also 2006 FDA data: Senate Hearings on Spinach Outbreak, Nov 15, 2006 80 (little on-farm activity); see Boys, Business of Safe Food for more detailed estimates of standards, certification bodies, etc…;

Wester 8-13-13 interview 2; Starmer & Kulick 3; Stier interview 2; Davis interview

For more detail see Lytton & McAllister

Chedwick interview 15-23; Thesmar interview 16-17; Loseke interview 2;

Gombas, Produce GAPs Harmonization

Gombas, Produce GAPs Harmonization

Pursley interview 1, 3; Wester 8/13/13 interview 1; Davis interview 1; Schwartz 8/9/13 interview 3

Pursley interview 1, 3; Schwartz 8/9/13 interview 3

Pursley interview 1; Stier interview 6; Gombas interview 11

Stier interview 2; Davis interview 2, Pursley interview 1, Costa interview 4-5; Theno 9/5/14 interview 9-10

Prevor 10-25-13 interview 3; Acheson 12/15/14 interview 4, 13; Prince 1/21/15 interview 8

Zagory interview 6; Stier interview 3; hard job Acheson 8-6-13 interview 2, 5; Prince 8-6-13 interview 8; IAEP Conference 2

Eric Schwartz interview 15; Gombas interview 11; Costa interview 4-5

Wester 8-13-13 interview 7; Costa interview 6; Powell, Audits and Inspectors 6; Pronk, Is Food Safety Auditing; Pronk, Third Party Audits; Sun, Food Inspection; for detailed analysis of the conflict, see Lytton & McAllister 300-303; $500-$1500 per audit or as high as $8500 in Starmer & Kulick, Bridging the GAPs 15; conflict of interest see Albersmeier, Reliability

Cuite, Public Response to the Contaminated Spinach Recall 7, 10, 13, 15, 17-19; Whitaker interview 8; Smith interview 9; get cites for Canada closure & Taco Bell outbreak

Whitaker interview 5-8, 11-12; McDonald interview 12.; Suslow interview 12; Schwartz interview 4-5; Giclas interview 5-6; Horsfall interview 2; Hardesty 2; CA, LGMA Handler Marketing Agreement; WGA, Good Agricultural Practices

Gombas interview 8

McDonald interview 3; Giclas interview 5

See discussion and cites in previous section

CA LGMA, Food Safety Standards 18, 27, 41, 47; Whitaker interview 9; Calvin, Outbreak Linked 6

Stuart 120; Wood, Marketing Agreements 69-70; Endres 67-72

CA LGMA, Handler Marketing Agreement 1-2, 9-10; see also Endres, Stuart, Hardesty, Kohnke, Shekhar, and Starmer; Horsfall interview 1

CA LGMA, Handler Marketing Agreement 1, 3, 4, 6, 11; Endres; Giclas interview 10
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63 Horsfall interview 3-4
64 Gombas interview 3; Cohen, History, Politics and Perils 9, 11, Endres 48-49; Giclas interview 9; Shekhar 285
65 McDonald interview 12; CA LGMA, Food Safety Standards 10
66 CA LGMA, Food Safety Standards 48; Suslow interview 11; Gombas interview 10
67 CA LGMA, Technical Advisory Board; Suslow interview 11, Whitaker interview 15-16; Center for Produce Safety http://www.centerforproduce安全性.org/about.php
68 Federal Register ANPR for the NLGMA; Federal Register Proposed Rule NLGMA 24292-3
69 Federal Register Proposed Rule NLGMA 2011; USDA Proposed NLGMA Summary 2011
70 this and next 2 paras: Runsten, CAFF Testimony; Cohen, History Politics; see also House of Rep Hearing 70
71 this and next paras: House of Rep Hearing on LGMA 76-85; Obadashian, Consumers Union Comments 2; USDA ANPR NLGMA
72 House of Rep Hearing on LGMA 76-85
73 Federal Register, USDA Terminates
74 White House, President Obama Weekly Address
75 White House, Obama Admin Delivers; Federal Register, FSMA Proposed Produce Safety Rule 3516; Federal Register FSMA Proposed Produce Safety Rule 3509-10
76 Federal Register, FSMA Proposed Produce Safety Rule 3508-10; Commodity Specific Food Safety Guidelines ii; Smith interview 8, 14; FDA, 2004 Action Plan 3; FDA, Guidance to Minimize Microbial Food Safety 2008
77 CSPI, Petition for GAPs 2006; CSPI, Letter to FDA; House Rep Hearing on LGMA 79; Wood, E coli Cases Prompt Calls
78 Covington, Bi Partisan; Covington, Food Safety Bill; Covington, House Passes; Covington, the Food and Drug; Marler, FSMA The End; FSMA Sec 105; Fed Reg FSMA Proposed 3516; Fed Reg FSMA Final Produce Rule 74354
79 Smith interview 14, 7; McDonald interview 21; Gombas interview 10
80 FSMA Sec. 105(a)(1); Fed Reg FSMA Final 74355, 74356, 74375; Produce Rule Sec. 112.44 (Fed Reg FSMA Final 74555); Sec 112.83 (Fed Reg FSMA Final 74558); 74373 (future guidance)
81 Fed Reg FSMA Final Produce 74368, 74370
82 Smith interview 6
83 Doering, Food Safety Modernization Act Lessons; cite for 2.2 million farms?
84 FDA, FSMA Operational Strategy
85 Taylor, We're Reinventing; Food Safety News, FDA's Taylor; see also Fed Reg FSMA Final 74519-21, 74373; Food Safety Summit 2; Fed Reg FSMA Proposed Produce Safety Rule 3608
86 Taylor FSMA Speech 2-16-12
87 Fed Register FSMA Final 74373; Petersen interview 17
88 Marler 5/31/16 interview 1; I changed “Portland” to Salem on basis of Lynn, Salem Woman
89 Marler interview 5/31/16; Marler, Files Fourth; Dole Lettuce E coli Outbreak Lawsuits; Marler, Will the Justice Department;
90 Marler interview 5/31/16 2; FDA, Warning Letter to Consumers Sept 20; Marler, Dole Sued by Oregon; Lynn, Salem Woman; Majeska v Dole complaint; Marler, Marler Clark Settles; Food Industry Center, Natural Selection 5-6; California Spinach Final Report 3; (Marler had filed lawsuits against Dole during the previous winter on behalf of victims sickened by bagged lettuce contaminated with E. coli O157.)
91 Baker, Six Ways 4
92 Mitchell interview 2-4; Hipp 4/16/15 interview 1; Theno 9/5/14 interview 14; Bermudez, Food Contamination Coverage 25-6; Mayerson, Insurance Recovery 844, 853-854; Skees 106-108; Western Growers, New Developments
93 Baker, Regulation by Liability Insurance; Logue & Ben Shahar, Outsourcing Regulation; see also Mojdzuska, Private and Public 11ff
94 Hipp 4/16/15 interview 1-4; Baker; Logue & Ben Shahar; Mayerson 845
95 Hipp interview 4/16/15 2-5; Becker interview 10
96 Hipp interview 4/16/15 2-5; Derr interview 7; Becker 6, 8-10, 13; Maxwell 5/26/16 phone call; Stauber interview 3; Mitchell interview 5-7, 10; Prince 1/21/115 interview 16; Giclas interview 15
97 Becker interview 13
98 Becker 8; Derr 7
99 Hipp 4/16/14 interview 5-6
100 Baker 1421; Logue & Ben Shahar 16; Mitchell 9; Hipp 4/16/15 interview 15
101 Baker Regulation, Logue & Ben Shahar; Mayerson 846
102 Hipp 4-16-15 interview 7-8; note that these terms & conditions primarily in nonadmitted insurers, Hipp interview 6/17/16 6-8
For examples of local surveys: a survey of 213 New York fruit and vegetable growers in 2002 found that “[m]ost growers used surface water for irrigation (76%), but few reported testing for water quality,” that “[g]rowers commonly washed produce on farm (92%) but rarely added sanitizers to this water,” and that “[o]f the 76 respondents (36% of the total) who applied manure or compost, most (88%) used practices that would reduce food safety risks based on federal guidelines … [but] only 52% of growers identified these practices as reducing food safety risk.” A survey of 297 New England fruit and vegetable growers in 2005 found that a majority employed good agricultural practices with regard to water quality, soil amendments, animal exclusion, worker hygiene, field sanitation, and recordkeeping. Calvin, Literature Review; Adalja, Impacts; Rangarajan, Focusing; Cohen, Farm Food USDA Fruit & Vegetable; http://blogs.usda.gov/2015/07/21/usda-introduces-new-food-safety-practices-survey-for-producers-processors/ (new USDA survey); USDA, Vegetable Chemical Use Survey 2016 PPT

Overview: Engreuter, First Look; Hardesty, Growers’ Compliance Costs; Toolian; CA LGMA Annual Report 2015 5; Jensen, Development

101 Baker 1421-2; Logue & Ben Shahar 12; Mitchell 7, 9, 16; XL Product Recall Food and Beverage Brochure, XL Product Recall Product Contamination Product Sheet; XL Product Recall Response Brochure; see also Becker 13, Mayerson 845; see Markley, Food Safety 14 for e.g.s of distributors who provide insurance to small farmers who get food safety training

104 Hipp 4/16/14 interview 5-6; Hipp 6/17/16 interview 18-19; See also XL Product Recall Response Brochure

105 For example, a survey of 213 New York fruit and vegetable growers in 2002 found that “[m]ost growers used surface water for irrigation (76%), but few reported testing for water quality,” that “[g]rowers commonly washed produce on farm (92%) but rarely added sanitizers to this water,” and that “[o]f the 76 respondents (36% of the total) who applied manure or compost, most (88%) used practices that would reduce food safety risks based on federal guidelines … [but] only 52% of growers identified these practices as reducing food safety risk.” A survey of 297 New England fruit and vegetable growers in 2005 found that a majority employed good agricultural practices with regard to water quality, soil amendments, animal exclusion, worker hygiene, field sanitation, and recordkeeping. Calvin, Literature Review; Adalja, Impacts; Rangarajan, Focusing; Cohen, Farm Food USDA Fruit & Vegetable; http://blogs.usda.gov/2015/07/21/usda-introduces-new-food-safety-practices-survey-for-producers-processors/ (new USDA survey); USDA, Vegetable Chemical Use Survey 2016 PPT

Overview: Engreuter, First Look; Hardesty, Growers’ Compliance Costs; Toolian; CA LGMA Annual Report 2015 5; Jensen, Development

106 Hardesty 5; Adalja, Impacts

107 CA LGMA, Expert Panel Review 6

108 Horsfall interview 13; see also Ward, Leafy Greens; see also CA LGMA Expert Panel 7; Marler 5-31-16 interview 8; DeWaal testimony in House of Rep Hearing on LGMA 82; CDC, FOOD Tool https://www.cdc.gov/foodborneoutbreaks/

109 ERG, Cost Effectiveness Measures Tomatoes; ERG, Cost Effectiveness of Practices Tomatoes; FDA, Technical Appendix; FDA, Final RIA 58. For fuller commentary, see Miller, Comment on RIA Produce Safety Rule 8-12

110 FDA, Final RIA 56

111 FSMA section 105 a & b; Johnson, Implementation of FSMA; Carey, Cost Benefit Analysis; cite APA 706 and relevant admin law summary (Mashaw casebook or text)

112 Calvin on GAPs data (phone call)

113 Buzby, Food Safety and Product Liability 637; see also Buzby, Product Liability and Microbial Foodborne Illness

114 Fan et al., Microbial Safety 397 fn 19; Marler 10-5-14 interview 8

115 Buzby, Food Safety 376; see also Buzby, Jury Decisions 237

116 See the discussion of framing effects in ch. 3

117 Dickerson cited in Mayerson, Insurance Recovery; Buzby, Product Liability 26; see discussion in ch 3

118 Marler 10/5/14 interview 13; IAFP 2014 Marler keynote notes I

119 Obadashian 2; House of Rep Hearing on LGMA 2000 83; see Lytton & McAllister, Oversight 304; On comparative institutional analysis, see ROSS E. CHEIT, SETTING SAFETY STANDARDS: REGULATION IN THE PUBLIC AND PRIVATE SECTORS 17, 193 (1990); NEIL KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY 3–13 (1994); PETER SCHUCK, THE LIMITS OF LAW: ESSAYS ON DEMOCRATIC GOVERNANCE 424 (2000); David Vogel, Taming Globalization?: Civil Regulation and Corporate Capitalism, in THE OXFORD HANDBOOK OF BUSINESS AND GOVERNMENT 473 (David Coen et al. eds., 2010); see generally Philip Harter & George Eads, Policy Instruments, Institutions, and Objectives: An Analytical Framework for Assessing “Alternatives” to Regulation, 37 ADMIN. L. REV. 221 (1985). For a recent comparative institutional analysis of public and private food safety regulation, see Fagotto, Private Roles in Food Safety

119 Fed Reg, FSMA Final Produce Safety Rule 74373

120 On hybridization see Havinga article and edited volume; cite Mojudska too

121 DiMaggio & Powell, Institutional Isomorphism 65-66; See Esty, Globalizing Admin Law

122 for a related point, see Busch, Standards law and governance 73

123 Meadows, Thinking in Systems loc 327, 755-882

124 Meadows loc 418, 1435; Holland, Complexity 5

125 For an early call for an “integrated (systems) analysis of public and private food safety control mechanisms, their interdependence and effectiveness,” see Mojudska, Private and Public 9; cite Havinga on hybrid regimes (forthcoming volume)

126 Meadows loc 354-371; Grobman, Complexity Theory 360-361; Holland 9-10

127 McDonald interview 2; Whitaker interview 17; Gornay interview 1-2

128 Pierami interview 6, Pursley interview 3; CSPI, Petition for GAPs; Senate Hearings
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130 Rees, Hostages; Carpenter, Reputation and Power loc. 981-1000
131 Abbott, Levi-Faur, Snidal Framework Paper, Lytton, Taming
132 This and next two paragraphs from Lytton, Taming
133 see Christakis, Connected loc 505 for the importance of network structure; this pyramidal structure nicely illustrated in Boys, Business of Safe Food 21 figure 1.
134 Meadows loc. 2873
135 Lytton, Taming
136 on markets as complex systems, see Holland
137 Hart, THE CONCEPT OF LAW 1961(rule of recognition); Lincoln, AUTHORITY (1994), 4-10 (authority as acceptance); Bernstein and Cashore, Can Non-State Global Governance be Legitimate?: Cashore, Legitimacy and Privatization
138 e.g. Fuchs, Kalfagianni and Havinga, Actors in Private Food Governance
139 Granovetter 2005, The Impact of Social Structure 33-34 (density); Lytton KOSHER 134-135; Yiannas, FOOD SAFETY CULTURE; Gunningham and Rees, Industry Self-Regulation
140 Granovetter, Social Structure 34-5
141 Giclas interview 2
142 Ferrary and Granovetter The Role of Venture Capital Firms, 332-333