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Technical Standards in Health & Safety Regulation: Risk Regimes, the New Administrative Law, and Food Safety Governance

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Abstract

A growing appreciation for the interaction and interdependence of private industry and public authority in developing regulatory standards, monitoring compliance, and disciplining those who fail to conform has led scholars to question the descriptive accuracy of the traditional distinction within regulatory theory between private ordering and public regulation. In its place, scholars have developed the concept of risk regimes to denote infrastructures of private and public entities engaged in regulatory governance. This conceptual shift has laid the foundation for a new understanding of administrative law, in which the rules and procedures that shape administrative governance are no longer limited to government rules that restrain government agencies. This broader conception of administrative law encompasses a wide array of norms — including constitutional doctrines, public laws, and private standards — that govern the regulatory activities of private entities. This chapter presents a case study of food safety regulation to illustrate the concept of risk regimes and the new administrative law that governs them.

Keywords: regulatory governance, risk regulation, food safety, standards conformity, health & safety regulation, regulatory pluralism, risk regimes

INTRODUCTION

Technical standards developed by nongovernment entities are an integral part of health and safety regulation. These "private" standards—produced by industry associations and standards development organizations—frequently inform health and safety guidance and rules issued by government agencies.[1] In some industries, private health and safety standards are more rigorous than government regulations. Private standards may also be the only source of health and safety norms in the absence of government regulation. In addition, private standards govern an array of consulting, auditing, testing, and certification services, which play an essential role in monitoring and incentivizing standards conformity and regulatory compliance related to health and safety.

A growing appreciation for the role of private standards in health and safety regulation has led scholars to question the descriptive accuracy of the traditional distinction within regulatory theory between private ordering

[1] I use the term "private" standards in this chapter as a shorthand for technical standards that derive from procedures conducted by nongovernment entities. However, as the analysis below will make clear, government representatives may participate extensively in the development of "private" standards. Scholars increasingly describe such government involvement in private standard-setting as a "hybrid" form of governance. I discuss hybridization in food safety governance below. For a detailed analysis of this concept, see, e.g. Verbruggen & Havinga 2017.

and public regulation and to replace it with the concept of risk regimes.[2] Discussions of regulatory policy often entail disagreement between advocates of less government intervention in industrial affairs and proponents of greater government involvement in, for example, protecting the environment, managing the economy, and advancing public health. However, the dichotomy underlying these terms of debate—the implicit choice between unregulated markets and government mandates—obscures the interaction and interdependence of private industry and public authority in developing regulatory standards, monitoring compliance, and disciplining those who fail to conform.[3] As one scholar explains, "social steering is becoming more and more a property of the interaction of organizations, networks, and associations involving both public and private actors, rather than a product of government control of and intervention in society."[4] Thus, concludes a second scholar, "contemporary governance might be best described as a regime of 'mixed administration' in which private actors and government share regulatory roles."[5] The concept of a risk regime denotes the infrastructure of private and public entities engaged in regulatory governance.

The role of private standards in governance is not unique to health and safety regulation, nor is awareness of it new. Social theorists dating back to the nineteenth century have appreciated that economic and social regulation have never really been the exclusive domain of government authorities and that private entities perform regulatory functions.[6] Contemporary elaboration of this insight has laid the foundation for a new understanding of administrative law, in which the rules and procedures that shape administrative governance are no longer limited to government rules that restrain government agencies. This broader conception of administrative law encompasses a wide array of norms—including constitutional doctrines, public laws, and private standards—that govern the activities of private entities.[7]

[2] Hood 2001; Freeman 2000, 857. See also Levi-Faur 2012, 13-14; Scott 2012, 61, 67.
[3] This dichotomy also obscures the role of government regulation in making markets possible. See Schepel 2014, 192-195. See also Salter, 179.
[4] Schepel 2005, 19-20. See also, Salter, 64.
[5] Freeman 2000, 816.
[6] Schepel 2005, 12-19. For a landmark study of the role of private standards in health and safety regulation, see Hamilton 1978.
[7] Freeman 2000, 854-858.

This chapter presents a case study of food safety regulation to illustrate the concept of risk regimes and the new administrative law that governs them. Food safety represents one of the oldest areas of health and safety governance and one of the most extensive. Food production is the world's largest industry, with a diverse array of sectors and global supply and distribution chains, which generate an estimated $7 trillion in annual revenues.[8] Within the area of food safety, the discussion below presents a detailed account of efforts to reduce microbial contamination of leafy greens in California's central valley. There are advantages and disadvantages to such a narrowly focused case study. Drilling down in one particular place yields a deeper analysis. However, any generalizations about the vast and varied terrain of health and safety governance must remain tentative.[9]

Before proceeding, an important caveat is in order. This chapter makes no claims about the efficacy or efficiency of either private standards or public regulation. Indeed, its conclusions will complicate attempts to evaluate efforts to advance health and safety. The focus is on how regulatory governance works, not on how well it works.

A. Industry Guidelines and Agency Guidance

Foodborne illness caused by microbial contamination is a significant public health concern in the United States. Researchers at the Centers for Disease Control and Prevention (CDC) estimate that each year in the U.S. foodborne pathogens cause 47.8 million cases of acute gastroenteritis, 128,000 hospitalizations, and 3,000 deaths.[10] According to a recent CDC report, contaminated fresh produce was responsible for 40 percent of reported foodborne illness cases.[11] Fresh produce presents a number of unique food safety challenges. It is grown in fields, where it is exposed to insects, feces from wildlife and livestock, and untreated water sources. Preventing contamination in the field is especially important because fresh produce is frequently consumed raw,

[8] IMAP 2010, 4.
[9] This case study is drawn from a more extensive account in Lytton 2019.
[10] Scallan 2011, 19.
[11] Centers for Disease Control and Prevention 2017, 7.

which forecloses the subsequent use of cooking to kill harmful pathogens during processing or home preparation.[12]

Food safety concerns about fresh produce are relatively recent. A 1985 National Academies report asserted that "raw fruits and vegetables are not common causes of foodborne illness in the United States," and that "there is little use for microbiological [safety standards] for fresh fruits and vegetables at the present time."[13] At that time, the U.S. Food and Drug Administration (FDA) had long possessed broad legal authority under the Federal Food, Drug and Cosmetic Act to prevent adulteration of any type of food sold in interstate commerce, but it had never developed implementing regulations for fresh produce as it had for processed foods.[14]

Complacency about the safety of fresh produce ended when, in the mid-1990s, public health officials began discovering foodborne illness outbreaks associated with fresh produce. 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.[15] Simultaneously, improvements in foodborne illness surveillance and tracing enhanced the ability of public health officials to connect outbreaks to particular products and companies.[16]

In response to growing concern about the safety of fresh produce, several industry associations coordinated efforts to develop technical standards—known as Good Agricultural Practices (GAPs)—aimed at reducing the risk of microbial contamination during growing and harvesting.[17] In one such effort, the Western Growers Association and the International Fresh-Cut Produce Association launched the Food Safety Initiative. 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. In addition, they convened a nineteen-member technical committee composed mostly of academics and industry experts with PhDs in food science, crop science, microbiology, virology, and toxicology. They also included in

[12] Bach & Delaquis 2009, 45; Niemira et al. 2009, 421.
[13] National Academy of Sciences 1985, 257-258.
[14] Burrows 2008; Shekhar 2010, 269, 273; Telephone interview with David Gombas by author 2016.
[15] Kohnke 2007, 499-500.
[16] U.S. Food and Drug Administration 2008, 3.
[17] For a more detailed description of GAPs, see Gravani 2009.

discussions and deliberations government officials from the FDA, the U.S. Department of Agriculture (USDA), the California and Arizona departments of agriculture, and the California department of health.[18]

In the summer of 1997, the Western Growers Association and the International Fresh-Cut Produce Association published a thirty-five-page booklet, *Voluntary Food Safety Guidelines for Fresh Produce*. 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 for Produce*, and academics at Cornell University published a tri-fold pamphlet, *Prevention of Foodborne Illness Begins on the Farm*.[19]

For the most part, these early GAPs merely highlighted potential problems without providing specific procedures or metrics for reducing risk. For example, with regard to irrigation water, the *Voluntary Food Safety Guidelines for Fresh Produce* encouraged growers "to identify and review the source of water used on the ranch" and suggested 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 offered slightly more direction: "growers are encouraged to clean and sanitize or disinfect tables, baskets and mechanical harvesters on a daily basis." The guidelines in a few instances referred growers to government regulations. For example, with regard to field sanitation, they stated that "the number, condition and positioning of toilets must meet all local, state and federal guidelines." The authors of the guidelines openly acknowledged the need for further scientific research and subsequent standards development to support more specific instructions to growers, stating that "the guidelines are not 'final,' as they will be revised periodically as experience, new research and new technology may suggest."[20]

In October 1997, President Clinton announced a government 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 earlier efforts of industry

[18] International Fresh-cut Produce Association & Western Growers Association 1997, iv-v.
[19] International Fresh-cut Produce Association & Western Growers Association 1997; United Fresh Fruit and Vegetable Association 1997; Rangarajan et. al. 1997.
[20] International Fresh-cut Produce Association & Western Growers Association 1997.

associations and academics. “This is probably a really good example of leveraging the work of other people,” recalls 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 leading U.S. 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 published a *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*.[21]

Like its industry and academic predecessors, the federal government’s 1998 guidance highlights areas of concern but lacks specific instructions. For example, the guidance advised that irrigation “water quality should be adequate for its intended use” and defined “adequate” as “that which is needed to accomplish the intended purpose in keeping with good practice.” The guidance stated that “growers may elect to test their water supply for microbial contamination” but, as one commentator points out, did 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.” Also like its industry and academic predecessors, the federal government’s 1998 guidance highlighted the inadequacy of scientific knowledge at the time and the need for additional research. In addition, like the industry and academic guidelines, the government’s guidance was nonbinding. It merely “represents the current thinking” of its authors, and compliance with its suggestions was entirely voluntary.[22]

Continuing outbreaks associated with fresh lettuce and tomatoes led the FDA to issue a 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*

[21] White House 1997; Telephone interview with Michelle Smith by author 2016; Telephone interview with Trevor Suslow by author 2016; U.S. Food and Drug Administration 1998.
[22] U.S. Food and Drug Administration 1998; Endres 2011, 61-62.

Safety Action Plan for fresh produce, pledging to "develop, and assist in the development of … commodity-specific and practice-specific guidance." In a subsequent November 2005 warning letter to the California leafy greens industry, the agency urged companies "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."[23]

Hank Giclas of the Western Growers Association recalls a series of meetings between industry representatives and FDA officials during this time. "We were in a long series of iterative discussions with regulatory agencies at that point in time, both at the state and federal level." During the discussions, FDA officials focused on "high risk" crops—such as tomatoes and leafy greens—associated with continuing outbreaks. According to Giclas, agency officials insisted, "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 agricultural 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."[24]

In April 2006, the Western Growers Association, the International Fresh-Cut Produce 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 emphasized that the guidelines were 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."[25]

[23] U.S. Food and Drug Administration 2004a; U.S. Food and Drug Administration 2004b; U.S. Food and Drug Administration 2005.
[24] Telephone interview with Hank Giclas by author 2016.
[25] International Fresh-cut Produce Association et al. 2006, iv.

The industry's commodity-specific GAPs did little to advance food safety in field operations beyond previous attempts. For example, the 2006 commodity-specific guidelines suggested that "water 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 one of the industry experts involved in developing the guidelines. 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.'"[26]

Although the 2006 industry guidelines placed no specific demands on growers, its authors hoped that they would encourage growers to pay more attention to food safety. Industry leaders, believing that the new guidelines would be taken more seriously if they came from federal regulators, asked FDA officials to co-author the guidelines or to publish them as agency guidance. However, FDA officials, despite having participated extensively in the process of formulating the guidelines, were unwilling at that time to adopt them as their own without subjecting them to additional review within the agency. In August 2006, the agency collaborated with the State of California to launch the Leafy Greens Safety Initiative, which sent officials to farms to assess current practices with the aim of further refining existing guidance to reduce the risk of microbial contamination in what Smith characterizes as a "two-way educational" process between regulators and growers. A few weeks later, the era of voluntary and vague guidelines in the California leafy greens industry came to an end.[27]

B. Marketing Agreements and Government Regulations

In September 2006, public health officials linked a rapidly growing number of illnesses caused by the deadly pathogen E. coli O157:H7 to fresh spinach. The magnitude of the outbreak far surpassed that of previous

[26] International Fresh-cut Produce Association et al. 2006; Telephone interview with David Gombas by author 2016.
[27] Telephone interview with Robert Brackett by author 2016; Telephone interview with Michelle Smith by author 2016; FDA 2013, 3512.

outbreaks linked to leafy greens. Government reports eventually blamed the outbreak for more than 200 reported illnesses in twenty-six states. One hundred and three victims required hospitalization, thirty-one suffered kidney failure, and three died. FDA warnings early in the outbreak to avoid eating bagged spinach until the precise source of contamination could be identified devastated the industry. According to one estimate, California leafy greens producers suffered nearly $100 million in losses following the outbreak.[28]

Investigators obtained from outbreak victims bags of Dole baby spinach that tested positive for the outbreak strain of *E. coli* O157:H7 and traced their contents back to four growing 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. 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.[29]

The 2006 baby spinach outbreak prompted leafy greens industry leaders to develop a more rigorous approach to regulating food safety on farms. Motivated by a desire to win back consumer confidence and to preempt efforts by state legislators to impose new government regulations, a half-dozen food safety managers from leading companies met informally. Their 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

[28] For detailed accounts of the outbreak and investigation described in this and the following paragraph, see Food Industry Center & National Center for Food Protection and Defense 2009 and Lytton 2019, ch. 5.
[29] California Department of Human Services Food and Drug Branch & U.S. Food and Drug Administration 2007.

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 Products Handler Marketing Agreement (LGMA).[30]

The California Marketing Act of 1937 authorizes the creation of marketing agreements. A marketing agreement is a voluntary commitment among a group of producers or handlers of a specific food commodity that sets common standards for production volume, quality characteristics, or packaging, with the aim of stabilizing prices. Marketing agreements allow agricultural producers and handlers to organize in ways that might otherwise violate antitrust laws designed to prevent collusion and price-fixing.[31]

The LGMA founders created a marketing agreement under the California Marketing Act that sets food safety standards for leafy greens growers. The agreement, however, is between 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 retailers, who sell greens to the public. Thus, handlers are the link between growers and retailers. Handlers who sign the marketing agreement commit to purchasing leafy greens exclusively from growers who pass periodic food safety audits of their operations by California Department of Food and Agriculture (CDFA) inspectors using LGMA standards. In exchange, signatory handlers may display a certification mark on their products and their promotional materials indicating membership in the LGMA and CDFA certification of their products.[32] 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.[33]

Following public hearings, the CDFA approved the LGMA. To assist the CDFA in the administration of the agreement, the LGMA establishes the California Leafy Green Products Handler Advisory Board, consisting of

[30] Interview with Robert Whitaker by author 2016; Interview with Hank Giclas by author 2016; California Department of Food and Agriculture Marketing Branch 2015.
[31] The California Marketing Act of 1937. On marketing agreements generally, see Wood 1961; Endres 2011 67-72. On the exemption of state action from federal antitrust laws, see Jorde 1987; California Department of Food and Agriculture Marketing Branch 2015, Art. XI, § A.
[32] The LGMA certification mark is a U.S. registered certification mark. California Department of Food and Agriculture Marketing Branch 2015, Art. V, § A. For a discussion of the issuance and use of certification marks, see Chapters 12, 13, and 14 in this volume.
[33] California Department of Food and Agriculture Marketing Branch 2015, Art. VI, § A.

handler signatories from different growing regions of the state and one representative of the general public, who must not be affiliated 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 growers' compliance with LGMA food safety standards. These third-party government audits are paid for by handlers through an annual assessment that finances the operating costs of the agreement as a condition of LGMA certification.[34]

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 California Secretary of Food and Agriculture as state regulations. However, the food safety standards by which the firms agree to abide are private industry standards. The CDFA's willingness to provide audits against those standards does not give the standards the status of agency regulations.[35]

The LGMA is more rigorous than earlier industry guidelines and government guidance because it provides specific standards for safety, makes implementation of them a practical necessity to gain entry into the national market, and relies on government inspection to monitor compliance. The LGMA founders attached quantitative measures, 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. The LGMA founders took a "three-tier approach" to developing metrics. As the introduction to the LGMA standards explains, "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

[34] California Department of Food and Agriculture Marketing Branch 2015. In food safety, third-party audits generally refer to audits of a supplier conducted by an outside auditor other than a buyer. The auditor is a third-party to the supplier-buyer relationship. Second-party audits are audits of a supplier conducted by a buyer. First-party audits, also known as internal audits, are audits of a supplier conducted by the supplier itself. Hammar 2015.
[35] Telephone interview with Scott Horsfall by the author 2016.

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."[36]

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 the metric for irrigation water of "adequate quality for its intended use," the LGMA adopted the Environmental Protection Agency (EPA) standard for recreational water, reasoning that "if it's safe enough to swim in, it must be safe enough to irrigate with," according to one industry expert.[37]

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.[38]

In response to 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 implemented 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.[39]

[36] California Department of Food and Agriculture Marketing Branch 2016. Telephone interview with Drew McDonald by author 2016.
[37] California Department of Food and Agriculture Marketing Branch 2016; Telephone interview with David Gombas by author 2016.
[38] California Department of Food and Agriculture Marketing Branch 2016.
[39] For a typical critique, see Stuart 2010. For a description of the process, see Western Growers Association 2010.

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 has a particularly high stake in preventing outbreaks, and it commands a level of market power that gives it 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. A few of these leading brand name handlers dominate the market. In 2006, Fresh Express (owned by Chiquita) accounted for 41% of all bagged, fresh-cut salad sales in the U.S., 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 dominated 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.[40]

LGMA reliance on government inspectors paid for by handlers avoids problems associated with private third-party food safety audits of farms. Typically, buyers of fresh produce—such as handlers or distributors or retailers—insist that growers obtain private third-party food safety audits to ensure their compliance with GAPs, and they insist that the growers select and pay auditors directly, creating a conflict of interest that incentivizes auditors to cut corners and inflate audit scores to please growers. Moreover, high demand coupled with inadequate training and experience has created a shortage of qualified private auditors. The LGMA's system of paying government inspectors from handler assessments eliminates both of these problems.[41]

Ongoing high-profile foodborne illness outbreaks involving many different sectors of the food industry generated growing public pressure for more rigorous federal oversight of food safety. Growers' desire to avoid a patchwork of varying state and local requirements and retailers' desire to improve food safety practices among

[40] Cohen 2008, 9-11; Endres 2011, 47-50; Shekhar 2010; Telephone interview with David Gombas by author 2016.
[41] For an extensive analysis of this system of private food safety auditing, see Lytton & McAllister 2014; Lytton 2019a; Lytton 2019b.

their suppliers prompted industry association support for federal legislation. Starting in 2008, a year after the rollout of the LGMA, various members of Congress introduced food safety reform legislation in both the House and the Senate. In the final days of December 2010, Congress passed the Food Safety Modernization Act (FSMA), which President Obama signed on January 4, 2011. Among its many provisions, the new law instructed the FDA to issue food safety regulations for the production of fresh produce—what became known as the FSMA Produce Safety Rule, which the agency issued in November 2015.[42]

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 one industry food safety expert, 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 another industry expert, "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."[43]

The FDA's shift from voluntary to mandatory standards had roots in both industry and government. Smith explains that "the initial response to regulating the industry was guidance, and that was fine with everyone. Around the time of the [2006] 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.

[42] Lytton 2019a, ch. 5; FDA Food Safety Modernization Act 2011; U.S. Food and Drug Administration 2015.
[43] Telephone interview with Michelle Smith by author 2016; Telephone interview with Drew McDonald by author 2016; Telephone interview with David Gombas by author 2016. The influence of private standards on government regulation frequently raises concerns about industry capture. For an extended discussion of capture theories in analyzing the evolution of food safety, see Lytton 2019a, ch. 3. On capture more generally, see Carpenter and Moss 2014.

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."[44]

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 more than 120,000 U.S. farms that cultivate fresh produce for sale.[45] 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. "There 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. FDA Deputy Commissioner for Foods and Veterinary Medicine Michael Taylor explained in a 2014 speech to the United Fresh Produce Association that the Agency was focused on supporting "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 an agency blog, Taylor explained that the agency 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 conduct "outreach and technical assistance to facilitate voluntary compliance." In explaining its proposed Produce Safety Rule in 2013, the agency wrote that "we anticipate that compliance will be achieved primarily through the conscientious efforts of

[44] Telephone interview with Michelle Smith by author 2016.
[45] U.S. Food and Drug Administration, 2017, 40.

farmers, complemented by the efforts of State and local governments, extension services, private audits and certifications, and other private sector supply chain management efforts."[46]

C. The Role of Private Standards and Conformity Assessment in Risk Regimes

The development and implementation of food safety governance within the California leafy greens industry blurs the distinction between private ordering and government regulation. GAPs emerged out of an iterative process that began with private standards initially formulated by an industry-sponsored technical committee that included government officials. Over time, this process produced voluntary industry guidelines, nonbinding federal agency guidance, marketing agreement requirements, and government regulations. Throughout, rulemaking occurred within an ongoing conversation among a mix of industry executives, government officials, and academic experts, conducted in both private and public institutional venues. At times, other groups, such as farmers and consumer advocates, also participated. Implementation increasingly relied on collaboration between private and public entities. Monitoring and enforcement of GAPs has contributed to the further intertwining—what some scholars refer to as the "hybridization"—of private and public food safety governance.[47] The resulting infrastructure of actors, institutions, and activities constitutes a risk regime.[48]

Individual companies and trade associations played a leading role in developing GAPs and gradually increasing their rigor. A combination of economic pressure, the prospect of state regulation, and increasing professionalization of food safety expertise motivated them. Foodborne illness outbreaks traced to leafy greens created economic pressure on firms to improve food safety throughout the industry. As the 2006 spinach outbreak so dramatically illustrated, an outbreak attributed to one firm threatened the profits of every firm in the

[46] U.S. Food and Drug Administration 2014; Taylor 2014; Food Safety News 2014; U.S. Food and Drug Administration 2013, 3608; U.S. Food and Drug Administration. 2015, 74373, 74519-21.
[47] Verbruggen & Havinga 2017.
[48] For further analysis of the concept of an infrastructure, see Edwards et al. 2012.

sector.[49] In addition, the prospect of state regulation following the 2006 baby spinach outbreak motivated industry leaders to impose rigorous LGMA metrics on growers. Industry leaders feared that legislators responding to political pressure from voters for tougher food safety laws would impose costly government mandates unsupported by either science or expert consensus. Industry lobbying efforts derailed legislative proposals within the California legislature to impose new government regulations on the industry and, within industry, the association used the prospect of heavy-handed state intervention to secure acceptance of the LGMA and accelerate their efforts to get it up and running.[50] Moreover, increasing professionalization of food safety within the fresh produce sector in the 1990s—in particular the arrival of PhD microbiologists in a field previously dominated by farmers and agronomists focused on pests and crop yields—helps explain the desire and capacity within industry to deal rationally with the uncertainty of newly emerging food safety risk by assembling committees of scientific experts to produce technical standards.[51]

Throughout the evolution of GAPs in the leafy greens sector, private standards have influenced government standards. Private standards provided the starting point for the drafting and elaboration of subsequent government standards. In particular, the initial industry guidelines analyzed GAPs into the categories of irrigation water, soil amendments, animal intrusion, workers, and harvesting equipment—a framework adopted by subsequent government guidance and regulation. Government guidance and regulation frequently incorporated private standards or adopted them with minor modifications.

Private entities have also played a leading role in the implementation of GAPs. Traditionally, neither federal nor state regulatory agencies responsible for food safety on farms have had sufficient resources to inspect growing operations except as part of investigations following foodborne illness outbreaks. Industry supply chain management has filled this void through private third-party food safety audits that assess growers' conformity to GAPs. Commercial buyers of fresh produce—processors, distributors, and retail sellers—have long relied on

[49] For extensive analysis of how reputational interdependence among firms motivates industry support for regulation, see Rees 1996; Yue and Ingram 2012.
[50] For a more detailed account, see Lytton 2019, Appendix D.
[51] On the role of professionalization in risk management, see Olshan 1993, 320, 324; specifically in food safety risk, see Lytton 2019, ch 5; Demortain 2011.

private third-party food safety audits of their suppliers, and these audits include, at a minimum, compliance with government guidance and regulations. The LGMA finances a system of fee-for-service audits by government inspectors to monitor compliance. Thus, in practice, farm-level compliance with food safety standards is driven by private supply chain management.

The analysis presented here emphasizes the role of private standards and conformity assessment within this risk regime. The aim is not to undervalue the contribution of government regulation, but rather to highlight its private underpinnings and its ongoing reliance on private forms of monitoring and enforcement. The distinction between private ordering and public regulation does not delineate alternative approaches to governance, but rather reveals interactions between highly integrated components of a common enterprise.

D. Concerns about the Legitimacy of Private Governance

Information about food safety risk is limited due to a combination of the high cost of collecting and analyzing relevant data, the complexity and opacity of causal connections between microbial contamination and harm, and the limits of current biomedical science. This means that the development of standards relies heavily on rough estimates and speculation, which may be controversial, even among experts.[52] Moreover, determining the appropriate level of risk reduction requires highly subjective judgments concerning the public's risk tolerance.[53] Discretionary decisions based on speculation and subjective judgments in the face of uncertainty run the risk of being considered illegitimate unless they emerge from procedures that allow for stakeholder participation and public accountability.[54]

In some ways, industry-sponsored efforts to develop safety standards for leafy greens sacrificed these indicia of legitimacy in pursuit of greater efficiency. Technical committees gathered in closed-door sessions to expedite

[52] On the costs of policy information, see Schuck 2014,161-170.
[53] On the importance of risk perceptions on risk analysis, see Ericson & Doyle 2004.
[54] On legitimacy generally, see Suchman 1995; on legitimacy in private governance, see Bernstein & Cashore 2007; Maurer 2017, 147-164; on legitimacy in private food safety governance, see Fuchs, Kalfagianni & Havinga 2009; for an extended critique on these grounds of the LGMA, see Stuart 2010.

the process of drafting standards. For example, Giclas recounts how beginning the process of developing the LGMA in a small group made it easier to advance the group's desire for more rigorous GAPs: "When we were developing the early draft, we had a smaller group in the room. They saw the problem, they were ramped up, and they were engaged. You can't do that with an entire industry. We would never have had a document if we tried to put everybody in the room at the same time."[55] Insularity fostered greater candor and reduced political posturing in meetings.

However, it is not true that stakeholders outside of industry had no voice in the deliberations of these technical committees. Government officials routinely participated in industry-sponsored technical committees to develop GAPs. Although there is no direct evidence, there is reason to believe that government agency officials may have been less inhibited in representing consumer interests in these industry-sponsored technical committees than they were in government-sponsored venues. When government agency officials convene a group to develop guidance or regulations, they are supposed to serve as impartial brokers between the interests of different stakeholders, including industry groups and consumer advocacy organizations. Agency officials are further constrained by a fear of running afoul of the diverse political agendas of their legislative and executive branch overseers. By contrast, when government agency officials participate in an industry-sponsored technical committee to develop private standards off of the public record, they can serve as more honest and zealous advocates for what they conceive to be the public interest.

The involvement of government officials notwithstanding, the lack of transparency may have made industry-sponsored technical committees less politically accountable than government-sponsored advisory committees would have been. Government-sponsored advisory committees are subject to open meeting and public record requirements under the Federal Advisory Committee Act. However, although industry technical committees were not subject to short-term political accountability, they saw themselves as subject to long-term market accountability if their efforts failed to avert subsequent outbreaks, prompting consumer dissatisfaction and, consequently, lost revenues and the prospect of government regulation. Hank Giclas of the Western Growers

[55] Telephone interview with Hank Giclas by author 2016.

Association recalls that, following the 2006 baby spinach outbreak, industry leaders feared these consequences if they did not establish more rigorous GAPs in the growing fields. "At Western Growers, we consider ourselves to be industry leaders. We saw the writing on the wall in the state if we did not act and do something."[56]

In the absence of specific baselines and metrics, assessing the legitimacy of institutions is often a matter of comparative analysis, in this case: How does private governance compare to the alternative of public regulation? Blurring the distinction between private ordering and government regulation complicates this type of comparative institutional analysis, which typically depends upon generalizations about distinct process-related features of private and public institutions—for example, the claim that private organizations are comparatively more efficient than government agencies but that they are less participatory and publicly accountable. As the evolution of food safety governance in the California leafy greens industry illustrates, industry increasingly emulated government notice-and-comment procedures in developing the LGMA metrics, and government has often sought to achieve greater efficiency through reliance on voluntary guidance and industry supply-chain pressure to incentivize regulatory compliance. The mimicry between industry and government efforts, further analyzed below, erodes categorical generalizations about comparative institutional virtues and vices.

Differences do remain, but capturing them requires leaving aside increasingly inaccurate generalizations in favor of more detailed analysis and specific metrics for measuring qualities such as participation and accountability. Comparative institutional analysis must find ways to determine, for example, the relative accountability of the Western Growers Association procedure for revising the LGMA metrics compared to the FDA's process for developing the Produce Safety Rule. The comparison is further complicated by the interdependence and intertwining of the two processes. If private standard setting is an integral part of an iterative process that also involves government rulemaking, it becomes unclear where, exactly, industry process ends and government process begins.

[56] Telephone interview with Hank Giclas by author 2016.

E. THE ADMINISTRATIVE LAW OF PRIVATE GOVERNANCE

Conformity to the rule of law adds an additional dimension of legitimacy to regulatory governance, a function performed by administrative law. Private standard setting and private third-party food safety auditing are constrained by a variety of norms that constitute the administrative law of private governance. Insofar as private standards are an integral part of risk regimes, this administrative law of private governance is an integral part of administrative law more generally. The "new" administrative law is, thus, an enlarged conception of the domain of administrative law that includes various types of norms governing private standard setting and private third-party auditing within risk regimes.[57] These norms shape the development and implementation of private health and safety standards, although, in the case of food safety, this influence is somewhat subtle.

Some of the norms that govern private standard setting and private third-party auditing arise out of constitutional norms that constrain government regulation. For example, the U.S. constitutional doctrine of nondelegation limits the scope of regulatory authority that a legislature may delegate to private entities. The federal nondelegation doctrine requires that Congress provide an "intelligible principle" to define the scope of any grant of legislative power to any public agency or private entity. Some states have stricter nondelegation doctrines. For example, the doctrine in Texas requires, in addition to an intelligible principle, meaningful oversight by government of private entities delegated legislative power; fair representation of stakeholders in rulemaking; general rulemaking rather than application of rules to particular parties; requirements that decisionmaking be unbiased and untainted by conflicts of interest; limitation to non-criminal matters; narrow limits on the duration, extent, and subject matter of the delegated authority; and sufficient qualifications and training to perform the delegated tasks.[58] In practice, these doctrines have rarely been invoked to strike down legislative delegations to private entities, and they have little application in food safety governance—where

[57] Freeman 1999.

[58] Federal and state constitutional doctrines of due process impose similar requirements on the exercise of governance authority delegated by legislatures to private entities. For an elaboration of both of nondelegation and due process doctrines as applied to private governance, see Volokh 2014; Schepel 2005.

government does not officially delegate rulemaking powers to private standard setters and government reliance on private third-party auditing is informal.

Public law is another source of norms that constrain private standards activity. For example, antitrust law limits the types of health and safety standards that an industry can attempt to impose on its members, as detailed in numerous chapters in the previous volume of this collection.[59] However, such antitrust concerns have played no appreciable role in structuring private food safety governance.

Legal restraints on government agency rulemaking regulate the incorporation of private standards, including food safety standards, into government regulations. These include provisions of the Administrative Procedures Act (APA) governing notice-and-comment rulemaking and executive orders requiring administrative regulations to satisfy cost-benefit analysis. The FDA conducted an extensive notice-and-comment process and cost-benefit analysis as the agency incorporated and modified LGMA and other private standards in the development of its Produce Safety Rule.[60]

In the case of food safety governance, these constitutional, public law, and administrative law norms have exerted influence on the process of private standard setting primarily through modelling rather than through enforceable legal regulation of delegation, competition, or incorporation. For example, the desire of the Western Growers Association to bolster the legitimacy of the LGMA metrics in the eyes of both producers and consumers led the association to develop rulemaking procedures modeled on the APA's notice-and-comment requirements. Following 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 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

[59] See, e.g., Chapters x, x and x (Vol. I). See also Volokh 2014; Schepel 2005; Cheit 1990, 187-190.
[60] For details, see Lytton 2019, ch. 6. On the incorporation of private standards into government regulations more generally, see Chapters 2 and 3 in this volume.

Secretary of Agriculture before a change is approved. The association and its members have thus sought to bolster the legitimacy and influence of the LGMA metrics by adopting these elements of government agency rulemaking associated with transparency, participation, and accountability.[61]

Private standards that govern standard-setting and conformity assessment are another source of constraints on private governance.[62] For example, the International Organization for Standardization (ISO) has published a series of technical standards that prescribe principles, policies, and practices for standard-setting bodies, auditors, certifiers, and the accreditation bodies that oversee them.[63] In food safety, standards for processing equipment are set by standard-setting bodies, such as Underwriters Laboratories (UL), the National Sanitation Foundation (NSF), and 3-A Sanitary Standards, Inc. (3-A SSI), which are accredited by the American National Standards Institute (ANSI) under ANSI's "essential requirements for openness, balance, consensus, and due process," which are consistent with ISO standards.[64] ANSI, in turn, is accredited by the International Accreditation Forum, which conforms to ISO standards for accreditation bodies. Similarly, private third-party food safety auditors must conduct their operations in accordance with ISO conformity assessment standards to obtain ANSI accreditation.[65]

It may seem odd to some readers to consider stretching the domain of administrative law to include private standards that govern standard setting and conformity assessment. However, socio-legal studies have long characterized institutionalized norms and bureaucratic routines as essential parts of the "law in action."[66] Socio-legal scholars use the term "legality" to include "the meanings, sources of authority, and cultural practices that are commonly recognized as legal, regardless of who employs them or for what ends."[67] Within the fresh produce industry, LGMA metrics, UL equipment specifications, food safety scheme audit criteria, ANSI

[61] For an analysis of institutional isomorphism generally, see DiMaggio & Powell; 1991; Olshan 1993; Meidinger 2006. For discussions of legality in private institutions, see Edelman & Suchman 2007, Esty 2006. For additional examples, see Halabi & Lin 2017.
[62] Schepel 2005, 5-8, 145-176; Schepel 2014.
[63] See, e.g., ISO/EIC 2017.
[64] ANSI 2018a; ANSI 2018b.
[65] International Accreditation Forum 2018.
[66] A classic example is the use of "rules of thumb" by insurance adjusters to settle tort claims. Ross 1980.
[67] Edelman & Suchman 2009, xiii (quoting Ewick and Silbey 1998, 22).

accreditation requirements, and ISO standards all operate as legal constraints on standard setting and conformity assessment.[68] Just as private standard setting is an integral part of agency rulemaking, and private auditing is essential to regulatory compliance, so too, the private principles, policies, and practices for standard setting and conformity assessment are part of the law that governs administrative regulation.

CONCLUSION

The history of food safety in the California leafy greens industry provides an example of the coevolution of industry standards and government regulation in health and safety governance. Analyzing this example using the concept of a risk regime highlights aspects of health and safety governance—namely the interdependence and intertwining of private and public efforts—that are obscured by a sharp distinction between private ordering and public regulation. Moreover, the concept of a risk regime illuminates how private standard setting can be a first step and an integral part of administrative rulemaking, which supports the idea that the study and practice of administrative law should include the principles, policies, and practices that govern private standards making and conformity assessment.

[68] Lytton & McAllister 2014.

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