Enactment of the Food Safety Modernization Act

The US FDA within the Context of Interacting Public-Private Governance Processes

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The United States' Food Safety Modernization Act (FSMA) revises the US Food and Drug Administration's regulatory authority. While expanding FDA's authority, the legislation replicates and relies on private systems of standards and third party audits, albeit with modifications. This article argues that public and private actors develop food safety regulations within multiple types of institutional venues, including private standards regimes, courts, congresses, and government regulatory agencies. It examines how interactions within each of these venues are shaped by stakeholders' interests, and how the relevant subset of interactions within these venues ultimately shaped the FSMA. The article concludes by offering insights into what consequences these interactions and outcomes may have on the roles and capacities of affected stakeholders in food safety governance.

I. Introduction

Scholars recognize that governance – the setting, implementing, and enforcing of rules[1] – is done by complex networks of state and non-state actors.[2] The literature emphasizes that there has been a shift from governing through traditionally hierarchical mechanisms to a focus on networks and mechanisms that do not rely solely on traditional authority of the state,[3] though the actors replacing or displacing the state may not themselves be non-hierarchical. Food safety governance over the last twenty to thirty years has followed this pattern, with food safety increasingly being governed through standards written by or at the behest of industry and enforced through third party audits.[4] The involvement of government actors in these standards and audits exists along a continuum, with some relying on government agencies to facilitate the rule setting and carry out audits.[5] A limited set of standards regimes are mandatory, and written and enforced wholly through government agents.[6] This paper will examine the evolving roles and relationships of government and private actors as they have been shaped by the enactment of the United States Food Safety Modernization Act (FSMA).[7]

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1 Anne Mette Kjaer, *Governance: Key Concepts* (Cambridge, Polity Press, 2004), at p. 10.

2 Bob Jessop, "The Rise of Governance and the Risks of Failure: The Case of Economic Development" 50 *International Social Science Journal* (1998), pp. 29 *et sqq*., Rod A.W. Rhodes, "The New Governance: Governing Without Government" 44 *Political Studies* (1996), pp. 652 *et sqq*.

3 Gerry Stoker, "Governance as Theory: Five Propositions" 50 *International Social Science Journal* (1998), pp. 17 *et sqq*.

4 Jason Konefal, Michael Mascarenhas and Maki Hatanaka, "Governance In The Global Agro-Food System: Backlighting The Role Of Transnational Supermarket Chains" 22 *Agriculture And Human Values* (2005), pp. 291 *et sqq*., Maki Hatanaka, Carmen Bain and Lawrence Busch, "Third-Party Certification In The Global Agrifood System" 30 *Food Policy* (2005), pp. 354 *et sqq*., Spencer Henson and Thomas Reardon, "Private Agri-Food Standards: Implications For Food Policy And The Agri-Food System" 30 *Food Policy* (2005), pp. 241 *et sqq*.

5 Ibid.

6 See, e.g., Hazard Analysis and Critical Control Point Requirements for Juice, 21 C.F.R. § 120.1 (2014), Seafood, 21 C.F.R. § 123.6 (2014), Meat, 9 C.F.R. § 304.3 (2014), and Poultry 9 C.F.R. § 381.22 (2014).

7 FDA Food Safety Modernization Act (FSMA), Pub. L. No. 111-353, 124 Stat. 3885 (2011), Amending the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (1938).

In the United States, some network complexity has long existed due to federalist arrangements between distinct levels of government and various public-private partnerships. In governing food safety, the federal Food and Drug Administration (FDA) has historically not had authority over food moving in intra-state commerce.[8] Instead, the agency collaborates with state regulators, public interest organizations, and industry to write a model food code that is variably adopted by states to regulate food wholly within states. An example of public-private partnerships for governing food safety is the Interstate Shellfish Sanitation Conference, which coordinates private, state and federal regulation of shellfish.[9] A more recent food safety governance development has been the use of marketing orders to establish and enforce food safety standards for production of fruits and vegetables.[10]

Though governance recognizes regulation occurring through diverse and complex networks of actors, centralized hierarchical governments may continue to play a significant albeit altered role.[11] The enactment of the FSMA is a valuable juncture for examining shifting interplays between emerging private governance regimes, centralized federal regulation, and decentralized state and local governance. The FSMA is an historic revision of US food safety law[12] that expands FDA's authority, but also builds on and relies on the pre-existing systems of private regulation. Most notably, the law requires FDA to replicate (but modify) preventive controls and produce safety standards like those already extensively in use in the private sector and to consider the use of private audits for regulating imported foods. Other provisions, such as certain exemptions and limiting the use of private audits to imported food, were shaped by stakeholders' experience with private and quasi-private regulatory regimes. In this case study, although the federal government is exercising centralized authority, the FDA is being forced to act in concert with a network of partners and other regulatory actors. The federal regulations, once written, will not create a single, universal standard for production, but instead will become another set of regulations in an already well-populated universe of regulations.

The recognition of governance through complex networks means studies of regulation cannot just focus on a single, centralized government policy cycle. Rather, one must examine multiple, simultaneously revolving policy cycles. With multiple policy cycles, there are also more complex streams of politics, problem recognition, and policy development, so that windows to set policy can open[13] in any number of institutional venues.[14] Venues may include Congress, the courts, state and federal regulatory agencies, private standard setting bodies, harmonizing organizations, and others. Actors and events in a particular stream, or the opening or closing of a policy window, may unexpectedly affect the policy making streams in other venues and add to the complexity of understanding how governance choices occurred.

To deal with this complexity, this paper focuses on the interactions of sub-sets of actors within the institutional venues where regulatory decisions are contested, decided, and enforced. While food safety governance is carried out by a complex network of state, industry, and civil society actors, only sub-sets of those actors may effectively participate in any given venue at any given time. Actors may concurrently fulfill different roles in the policy process depending on which venue is in play. Thus, as actors in a private regulatory regime are implementing and evaluating a regulation, they may simultaneously be involved

8 Food, Drug and Cosmetic Act, 21 U.S.C. § 303, prohibiting inter-state shipments of adulterated food.

9 Interstate Shellfish Sanitation Conference homepage, available on the Internet at: http://www.issc.org/Default.aspx (last visited 2 Feb. 2015).

10 See e.g. the California and Arizona Leafy Greens Agreements, discussed in more detail *infra* section II.1.b. Marketing orders are public-private regulatory mechanisms developed in the 1930's to coordinate production and marketing of perishable crops.

11 John Pierre and Guy Peters, *Governance, Politics and the State*, (New York, NY: St. Martin's Press 2000).

12 Helena Bottemiller, "Historic Food Safety Bill Signed Into Law", Food Safety News, 5 January 2011.

13 John Kingdon, *Agendas, Alternatives and Public Policies,* 2nd ed. (New York, NY: Longman 2003)

14 The term 'venues' draws from Baumgartner and Jones research into how actors interactions in venues can be used to contest a policy image and destabilize policy networks. As they note:There are no immutable rules that determine which institutions in society will be granted jurisdiction over particular issues. Depending on the issue and on how it is understood by those potentially involved, it may be assigned to an agency of the federal government, to private market mechanisms, to state or local authorities, to the family, or to any of a number of institutions. We term this the venue problem. Each venue carries with it a decisional bias, because both participants and decision-making routines differ. When the venue of a public policy changes, as often occurs over time, those who previously dominated the policy process may find themselves in the minority, and erstwhile losers may be transformed into winners.
Frank Baumgartner and Bryan Jones, "Agenda Dynamics And Policy Subsystems" 53 *The Journal of Politics* (1991), pp. 1044 *et sqq.*, at p. 1047.

in the standard setting phase for a public regulatory regime. This has been the case with the FSMA. For example, manufacturers who have been subject to private standards and produce growers who were setting standards enforced by state and USDA agents both called for FDA to take on the role of adopting and enforcing standards for the production of food and oversight of auditors. Likewise, the auditors responsible for enforcing standards are simultaneously advocating for greater reliance on private audit systems while also rewriting private standards for the auditors' competencies in response to some of the same issues that catalyzed the FSMA.

Identifying and accurately categorizing the primary influential stakeholders can help in examining how actors' identities, interests and relationships shape policy choices and how the regulatory systems relate to one another. [15] Scholars commonly divide actors into state, market, and civil society actors. These broad categories oversimplify actors' roles within the categories as well as how porous the categories have become. Therefore, it is useful to distinguish between different actors within each category. [16] During the enactment of the FSMA, noteworthy differences within each of these categories ultimately had a significant impact on the law. Within the 'state actors' category, the three most important ones to consider for this paper are members of Congress, the US Food and Drug Administration officials, and state departments of agriculture agents. Within 'market actors', although the legislative process saw significant commonalities, there were subtle differences between retailers, importers and distributors, manufacturers, growers, and auditing firms in terms of what they considered most significant. In the civil actors' categories, there was an unexpected and dramatic rift between consumer groups and alternative food systems advocates. The importance of these distinctions will become evident as the venues where they interact are discussed.

Using the trope of venues allows one to focus on how certain actors' interactions within each venue shape stakeholders' objectives, and in turn how those actors then adjust their strategy and ultimately shape regulatory practices in other venues in which they participate. To examine how private regulatory regimes are shaping public food safety regulation in the United States, this paper focuses on how the prior interactions between sub-networks of actors in other regulatory venues shaped what concerns and strategies actors brought to enactment of the FSMA, which occurred in the Federal congressional venue. This paper begins with analysis of the important venues where actors previously interacted and what concerns they took from those venues. It then turns to discussing how those interactions shaped the enactment process and final provisions that made it into the law. Finally, this paper discusses how the FSMA reshapes and impacts the roles and capacities of actors in the new and pre-existing regulatory regimes.

II. Interactions pre-FSMA

Before the process of enactment of the FSMA, many of the key actors were members of networks engaged in governance in other venues. Most prominently, manufacturers and fresh produce growers were being subjected to private standards regimes driven by retailers and multi-national food companies operating in globalized markets.[17] Additionally, fresh produce growers were implementing industry-wide regulations through quasi-public mechanisms.[18] Though less prominent, consumers and the FDA were also interacting with and shaping the evolution of these regimes through their exercise of power in the US court system. Finally, international standards and dispute resolution bodies cast a shadow over the enactment phase to the extent that stakeholders were concerned about how US law could be affected by global trade rules. Successes and failures of public and private actors in each of these venues impacted the provisions stakeholders prioritized in the enactment of the FSMA.

15 Fabrizio Cafaggi, "The Architecture Of Transnational Private Regulation" 2011/12 *European University Institute Working Papers* (2011); Fabrizio Cafaggi, "New Foundations Of Transnational Private Regulation" 38 *Journal of Law and Society* (2011) pp. 20 *et sqq*., 45; Tetty Havinga, "Conceptualizing Regulatory Arrangements: Complex Networks of Actors and Regulatory Roles" in Tetty Havinga, Frans van Waarden and Donal Casey, *The Changing Landscape of Food Governance* (Cheltenham, Edward Elgar 2015), p. 19-36..

16 Havinga, "Conceptualizing Regulatory Arrangements", *supra* note 15.

17 Hatanaka, Bain and Busch, "Third-Party Certification In The Global Agrifood System", *supra* note 4, Konefal, Mascarenhas and Hatanaka, "Governance In The Global Agro-Food System", *supra* note 4.

18 Diana Stuart, "Science, Standards, And Power: New Food Safety Governance in California" 25 *Journal Of Rural Social Sciences* (2010), pp. 111 *et sqq.,* Hoy Carman, "California Farmers Adapt Mandated Marketing Programs to the 21st Century" 61 *California Agriculture* (2007), pp. 177 *et sqq*..

1. Industry Driven Regulatory Regimes

Private regulation has encountered two recurring problems. First, the proliferation of private standards and audit requirements created multiple audits that were time consuming and expensive. The different audits showed little evidence of providing unique advantages or superior effectiveness relative to one another. Second, recurrent food borne illness outbreaks, some associated with companies that had received seemingly superior scores from private audit firms, eroded consumer and industry confidence in the effectiveness of these private audit regimes. [19]

Initially, industry sought to reform the private standard setting and enforcement mechanisms to shore up the effectiveness and perceived legitimacy of the private regimes through programs discussed here such as Global Food Safety Initiative and the Leafy Greens Marketing Agreement.[20] Ultimately, industry allied with consumer groups to call for the enactment of the FSMA, while also continuing to pursue food safety regulation through industry organized schemes.

a. GFSI Schemes: Evolution, Breakdown, and Calls for the FSMA

The Global Food Safety Initiative (GFSI) describes itself as a benchmarking system initiated in 2000 by the Consumer Goods Forum, an international trade association of retailers and manufacturers, to address the proliferation of standards and audits for food manufacturers. This collaboration attempts to reduce the number of audits required of producers by establishing minimal acceptable requirements "to credibly determine equivalency between food safety schemes, whilst leaving flexibility and choice in the marketplace."[21] Over its tenure, GFSI has made progress on harmonizing standards and auditing practices, while also pushing for continuous improvement.[22]

In 2008, Wal-Mart began to require GFSI recognized audits of certain suppliers, catalyzing more widespread adoption of GFSI in the United States.[23] Consequently, manufacturers and growers selling to large buyers were told to achieve increasingly stringent private standards while their competitors and other segments of their industry were held to outdated public food safety standards. Buyers, meanwhile, were not vigorous about restricting purchases to GFSI-certified producers, which undermined incentives to invest in food safety.[24] As outbreaks of foodborne illnesses continued through the 2000's, industry trade associations such as the United Fresh Produce Association, the Grocery Manufacturers Association, and the Food Marketing Institute all turned to supporting the idea of food safety legislation reform to hold everyone to a minimum set of common standards. [25]

There were differences between consumer groups and industry groups over the extent to which FDA should rely on or regulate private regulation. The history of outbreaks associated with privately audited

19 Gallup polls during this time period showed little change in consumer perceptions regarding food safety. Gallup, "Nutrition and Food", available on the Internet at: http://www.gallup.com/poll/6424/Nutrition-Food.aspx (last visited 2 Feb. 2015). However, industry and consumer group publications were widely reporting declining consumer confidence in the US food supply. See, e.g., Peter D. Hart Research Associates and Public Opinion Strategies, "Results Of A National Survey On Produce Safety", available on the Internet at: http://www.pewtrusts.org/~/media/legacy/uploadedfiles/phg/content_level_pages/reports/PSPRPTHartResearchSurveypdf.pdf (last visited 2 Feb. 2015), Rory Harrington, "Bill bids to strengthen 'dangerous' US food safety regimes", Food Navigator USA, 29 May 2009, available on the Internet at http://www.foodnavigator-usa.com/Regulation/Bill-bids-to-strengthen-dangerous-US-food-safety-regime (last visited 2 Feb. 2015), Jenny McTaggart, "Food Safety: Safety Dance", Progressive Grocer, 15 Oct. 2007, available on the Internet at: http://business.highbeam.com/4122/article-1G1-170296861/cover-story-food-safety-safety-dance (citing FMI research showing consumer confidence at 18 year low.)

20 The LGMA is not technically a private regulatory regime. Instead, it is a regulatory tool that was developed under state-level marketing agreement laws. Since it was industry initiated and driven, but overseen by public process, it is a quasi-public-private regulatory arrangement.

21 GFSI, "What Is GFSI", available on the Internet at: http://www.mygfsi.com/about-us/about-gfsi/what-is-gfsi.html (last accessed on 17 October 2014).

22 John G. Surak and Kathy L. Gombas, "GFSI's Role in Harmonizing Food Safety Standards", Food Safety Magazine, June/July 2009.

23 Wal-Mart, "Wal-Mart Becomes First Nationwide U.S. Grocer to Adopt Global Food Safety Initiative Standards," 4 February 2008, available on the Internet at: <http://news.walmart.com/news-archive/2008/02/04/wal-mart-becomes-first-nationwide-us-grocer-to-adopt-global-food-safety-initiative-standards> (last accessed on 17 October 2014).

24 Jim Prevor, "Buyer Led Food Safety Initiative Recap", Perishable Pundit, available on the Internet at: http://www.perishablepundit.com/index.php?hot=buyer-led (last accessed on 13 October 2014).

25 See, e.g., "United Fresh Statement on Introduction of the FDA Food Safety Modernization Act of 2009", 9 March 2009, available on the Internet at: http://www.unitedfresh.org/food-safety/food-safety-modernization-act/ (last accessed on 17 October 2014), "Grocery Manufacturers Association And Food Marketing Institute Call For Passage Of Food Safety Bill", 24 November 2010, available on the Internet at: http://www.gmaonline.org/news-events/newsroom/grocery-manufacturers-association-and-food-marketing-institute-call-for-pas/ (last accessed on 17 October 2014).

foods had seriously eroded trust in the quality of the standards and the quality of the inspections and consumer groups saw enforcement of food safety as a quintessentially government role.[26] Industry representatives, meanwhile, argued that private standards and auditing schemes were effective. They expect private auditors to be as effective as (if not superior to) government inspectors due to auditor accreditation and economic accountability.[27]

Discussions over the appropriate role of private regulatory regimes within a public system were complicated by the fact that two of the major outbreaks driving the bill – separate salmonella outbreaks in peanut butter and eggs – were traced back to domestic facilities that had received seemingly superior ratings from private audit firms.[28] Yet government officials had been in those facilities as well and failed to detect transgressions and take actions to prevent the outbreaks.[29] Consumer groups saw these incidents as symptomatic of the flaws inherent in a private self-regulatory system combined with failures resulting from under-resourced public regulatory regimes. Although industry joined with consumer groups in calling for stronger FDA oversight, industry spokespersons also argued for the quality and effectiveness of industry developed regulatory regimes.[30] Interviews with industry actors have suggested that the outbreaks were caused by anomalous bad actors and that government is no better at detecting, especially those who knowingly disregard standards and hide food safety violations, as happened in the PCA incident.[31]

Many, including FDA officials and consumer groups, acknowledged the necessity of relying on private audits as supportive of the FDA's food safety role, given the agency's limited resources and constrained authority in foreign countries. The Center for Science in the Public Interest (CSPI), the Grocery Manufacturers Association (GMA), and the FDA all put out proposals that envisioned FDA relying on private auditors to enhance governance of imported foods. However, there was disagreement regarding what FDA's and private auditors' roles should be domestically. Consumer groups wanted significantly expanded authorities for FDA, including requiring process controls for all manufacturers, increased records access, more diverse penalties, and increased enforcement authority for FDA – with no role for private audits. GMA's plan on the other hand called for little more than increasing FDA's capacity to collect data and transition to risk-based enforcement. FDA's plan fell in the middle, calling for increased reliance on manufacturers through requiring food-safety plans for high risk foods, and partnering with private accredited auditors to enforce food safety domestically and abroad.[32]

b. Produce Standards and the Leafy Greens Marketing Agreements

In the early 1990s, produce associations began to recognize outbreaks being associated with fresh produce and moved to develop voluntary guidelines –

26 See Patricia Sabatini, "Calls Grow For Tougher Food Safety Regulations," Pittsburgh Post-Gazette , 7 October 2009, at FOOD p. A1, (quoting CSPI attorney Sarah Klein saying "the FDA needs tough, 21st-century tools to deal with centralized, modern production…we cannot rely on the good will of the food industry.")

27 See Timothy Lytton and Lesley Mcallister, "Oversight In Private Food Safety Auditing: Addressing Auditor Conflict Of Interest" 2014 Wisconsin Law Review (2014), pp. 290 *et sqq.*

28 The Peanut Corporation of America and Decoster Farms had both received "superior" ratings from AIB shortly before their products sickened hundreds. See *The Outbreak of Salmonella in Eggs, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 111th Congress (2010) (statements by Peter DeCoster, co-owner of DeCoster Farms; statement by DeGette, vice-chairman, H. Comm. on Energy and Commerce) at p. 82. See also Andrew Martin, "Peanut Plant Says Audits Declared it in Top Shape", New York Times, 5 February 2009, at p. B10, Michael Booth and Jennifer Brown, "Producers Seldom Hear of Food Safety Issues from their Private Auditor", The Denver Post, 30 October 2011, at p. A1.

29 Alan Judd, "Peanut Scare Exposes Flaws in Inspections; Food Safety Net: Regulation Gaps Found at Georgia Processing Plant Will Likely Come Under Scrutiny In Upcoming Congressional Hearings", *Atlanta Constitution Journal,* 30 January 2009, at p. 1A.

30 See, e.g., *How Do We Fix Our Ailing Food Safety System? before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 111th Congress* (2009) (statement of Tom Stenzel, President and CEO, United Fresh Produce Association), *Keeping America's Families Safe: Reforming the Food Safety System, before the S. Comm. on Health, Education, Labor, and Pensions*, 111th Congress (2009) (statement by Michael Roberson, Director of Corporate Quality Assurance Publix Markets Inc., on behalf of the Food Marketing Institute).

31 Anonymous interviews conducted by the author with civil society, government, and industry representatives between October 2013 and September 2014. Interview subjects were initially identified using news stories and legislative testimony from the FSMA; further interview subjects were identified through snowball sampling by asking initial subjects for other important actors to speak with.

32 See Caroline Smith-Dewaal and David W. Plunkett, "Building A Modern Food Safety System For FDA Regulated Foods", (Center For Science In The Public Interest, 2009), "Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply" (Food And Drug Administration, 2007); "A Commitment to Consumers to Ensure the Safety of Imported Foods: Four Pillars of Public-Private Partnership" (Grocery Manufacturers of America).

known as Good Agricultural Practices (GAPs) – which can be enforced through private audits or through programs run by states and the United States Department of Agriculture. Being voluntary, the programs are not universally employed and various segments of the produce industry have lost millions of dollars following outbreaks associated with product from a single grower.[33]

In 2008, tomato growers in Florida claimed to lose an entire season's crop and revenue when a *Salmonella* Saintpaul outbreak was erroneously initially attributed to tomatoes from Florida. The industry had an extensive food safety and trace back regime which they argued to FDA officials demonstrated the safety of their product. Despite the system, FDA believed that their epidemiology sufficiently justified issuing consumption warnings that diminished demand for the crop and caused Florida tomato growers' significant economic harm. The tomato growers were ultimately proven right when the outbreak was conclusively connected to hot peppers.[34] For the produce industry, this incident highlighted the need to have FDA recognize industry's food safety practices.

Two years earlier, following a particularly deadly and widespread outbreak of E. coli associated with leafy greens from California, [35] the California and Arizona leafy greens industries initiated the California and Arizona Leafy Greens Marketing Agreements (LGMA).[36] In response to plummeting consumer demand for leafy greens, the industry initiated a request to the California Department of Agriculture to develop the marketing agreements through a public proposal, feedback and voting process.[37] This approach was explicitly chosen as the fastest way to respond to retailer and consumer demands for food safety, while also bringing government officials onto the farm to ensure confidence in the quality of the inspections.[38] The process was not uncontroversial, with small farms and conservation advocates raising concerns about the economic and environmental impacts of the rules being written. [39] Another criticism was that if all producers and handlers failed to sign on to the agreement, the standards would be ineffective at ensuring food safety and rebuilding consumer trust.[40] At the same time, the California legislature considered legislation to mandate standards and increase agency enforcement over leafy greens. This was out of concern that industry self-regulation through the LGMA would be ineffective.[41]

In the end, the LGMA was adopted and it established metrics for evaluating safety of production in fields in California and Arizona, with compliance verified through audits carried out by government inspectors. The agreements have gained extensive adoption, with approximately 90 percent of greens grown in the US subject to either the California or Arizona agreement.[42] Nonetheless, the remaining leafy green producers across the country remained free of, and generally opposed to, metrics for safety of leafy greens. In a reprise of the issues, a national leafy greens agreement overseen by the US Department of Agriculture, was proposed but ultimately dropped due to the enactment of the FSMA.[43]

Despite the extensive efforts at private regulation and partnerships with state and federal agriculture departments, important produce trade associations took the position that universally enforced food safety standards written and recognized by FDA officials

33 See Luis A. Ribera et al., "Costs of Foodborne Illness Outbreaks for Vegetable Producers", EHT-027 *Texas A&M Agrilife Extension* (December 2013).

34 See Vanessa Wong, "Rotten Tomatoes: Farmers Pay the Price for A False Food Safety Warning", Bloomberg Business Week, 29 September 2014.

35 Jesse Mckinley, "Center Of E. Coli Outbreak Is Also Center Of Anxiety", New York Times, 25 September 2006, at p. A14.

36 Each state technically has a separate LGMA, because they are developed under state law. However, it is common to refer to them jointly as the LGMA.

37 California Marketing Act of 1937, 21 Food & Agric. § 58601-58624 et seq., 3 Ariz. Rev. Stat. § 3-401 et seq.

38 Scott Horsfall, "California Leafy Greens Marketing Agreement Emerges as a Model Program for Food Safety", Food Safety Magazine, August/September 2008.

39 See Stuart, "Science, Standards, and Power", *supra* note 13 for an in-depth discussion of the motivations and controversies involving the LGMA. Efforts have since been underway to address some of these issues. See, e.g., Karen Lowell, Jeffrey Langholz, and Diana Stuart, "Safe and Sustainable: Co-Managing for Food Safety and Ecological Health in California's Central Coast Region" (The Nature Conservancy of California and the Georgetown University Produce Safety Project, 2010).

40 See Jim Prevor, "Is the California Marketing Agreement a Triumph or a Failure?", Perishable Pundit, 9 February 2007.

41 See Rong-Gong Lin II, "Senator Seeks New Oversight of Greens", Los Angeles Times, 12 October 2006, available on the Internet at: < http://articles.latimes.com/2006/oct/12/local/me-spinach12> (last accessed on 31 October 2014).

42 California Leafy Greens Products Handler Marketing Agreement, "About Us", available on the Internet at: http://www.lgma.ca.gov/about-us/ (last accessed on 17 October 2014).

43 National Marketing Agreement Regulating Leafy Green Vegetables; Termination of Proceeding on Proposed Marketing Agreement, 78 Fed. Reg. 234 at 73111.

were needed.[44] However, opposition from small farm and sustainable agriculture advocates stemming from experiences with the LGMA nearly killed the legislation. The compromise that was worked out, exempting certain small farms and facilities selling directly to consumers within a geographic region, was opposed by industry, consumer groups, and the FDA. The law passed containing the exemption because of the perceived importance of achieving legislative reform.[45]

2. Courts

State and federal courts in the United States are an important and under-attended to venue where the public and private regulatory regimes meet. First, courts are a venue where the rules concerning interactions between food safety regulators and regulated entities are partly written and enforced. The Food, Drug and Cosmetic Act required the FDA to obtain a court order to mandate recall of a product,[46] thereby limiting FDA's enforcement flexibility. Though the agency also had criminal sanctions authority, the FDA rarely used it.[47] New enforcement provisions in the FSMA will give the agency more flexibility for enforcing food safety, but have raised concerns among industry that the agency may abuse its power because systems of judicial accountability have been bypassed.[48] Similarly, industry suits challenging FDA's exercise of power as unconstitutional takings of property and inappropriate restrictions on trade have attempted to further limit FDA's exercise of authority. The suits have, so far, been relatively unsuccessful.[49] However, there is concern these suits could have chilling effects on the agency's enforcement strategies.[50]

Courts have also been an important venue for consumers to pursue accountability in the food system when government officials have failed to detect and/or deter unscrupulous and inadvertent bad actors.[51] This exposure to legal liability led retailers, manufacturers, and growers to adopt private and voluntary standards and audit schemes to regulate food safety.[52] In the United States, consumers can potentially hold everyone throughout the supply chain liable for injuries from contaminated foods. However, standards and audit requirements, combined with indemnity clauses in contracts, have the effect of shielding retailers from liability.[53] Consequently, accountability in the supply chain does not fall on the entities whose financial clout significantly influences compliance with food safety requirements. Though the FSMA significantly alters FDA's authority and consequent relationship to the regulated industry within the courts, it does little to change the liability dynamics between buyers and sellers.

3. International Venues

The final venues to be discussed are the World Trade Organization and the Codex Alimentarius Commission. The Agreement on the Application of Sanitary and Phytosanitary Measures of the WTO requires countries' food safety standards to conform to standards written by the Codex.[54] One standard that

44 See Jim Prevor, "PMA and United Fresh Agree on Federal Food Safety Regulation", Perishable Pundit, 24 May 2007.

45 See Bill Marler, "Once GOP Is In Kitchen, Food Safety Is Toast", Food Safety News, 3 December 2010.

46 Food Drug and Cosmetic Act, 21 U.S.C. § 331 et seq. (2009).

47 Dan Flynn, "Reprieve from Criminal Prosecutions May Be Ended For Food Execs", Food Safety News, 4 May 2012.

48 See David Acheson, "FDA FSMA Facility Suspension Powers – Appropriate or Abusive?", 20 March 2014, available on the Internet at: <http://achesongroup.com/2014/03/fda-fsma-facility-suspension-powers/> (last accessed on 12 October 2014).

49 Dan Flynn, "Top Food Safety Stories Of 2011: No. 5", Food Safety News, 27 December 2011, Dan Flynn, "Tomato Growers Lose 'Takings' Lawsuit against FDA", Food Safety News, 22 September 2014.

50 Mary Clare Jalonick, "Suit Could Chill Government Efforts To Keep Food Safe", Bloomberg Businessweek, 31 August 2011.

51 See, e.g., *Hearing to Review Current Issues in Food Safety, Hearing Before the H. Committee On Agriculture,* 111th Cong. (2009) (Statement of Rep. Bob Goodlatte, Member, House Comm. On Agriculture). "That incident [the PCA outbreak] was not the result of inadequate legal authority or even inadequate regulation. It was the result of intentional disregard of food safety standards by the food processor and a complete failure of the FDA to enforce its own regulations."

52 Linda Fulponi, "Private Voluntary Standards In The Food System: The Perspective Of Major Food Retailers In OECD Countries" 31 *Food Policy* (2006), pp. 1 *et sqq*., Hatanaka, Bain and Busch, "Third-Party Certification In The Global Agrifood System", *supra* note 4.

53 See Bill Marler, "Why Food Retailers Really Don't Care", 14 June 2013, available on the Internet at: http://www.marlerblog.com/lawyer-oped/why-food-retailers-really-dont-care/#.u2z4c_ldwso (last accessed on 4 May 2014), Bill Marler, "What Do Cantaloupe and Baseball Have In Common? At Least a Baseball Won't Kill You", Food Safety News, 17 August 2013.

54 Uruguay Round of Multilateral Trade Negotiations (1986- 1994) , Agreement on the Application of Sanitary and Phytosanitary Measures (WTO- GATT 1994), 15 April 1994, in force 01 Jan. 1995, Art. 12.3.

Codex has written is for Hazard Analysis and Critical Control Point Systems (HACCP). Among the actors who participate in Codex are FDA officials, who recognize that the standards set in Codex can constrain how the agency regulates. When the FSMA was enacted, rather than require HACCP systems of all manufacturers, Congress chose to require "risk based preventive controls plans" which are HACCP-like. One interview suggested this was so that FDA would not be constrained to conforming to Codex standards. Several others noted that the provision means FDA's regulations will not necessarily be consistent with globally recognized standards, including the private GFSI regulations that are based on Codex.

Another venue to note is the International Organization for Standardization (ISO). The ISO has not had a mentionable impact on enactment of the FSMA. However, applicable ISO standards are used by the GFSI to assess food safety schemes.[55] The accreditation of certifying bodies to ISO standards is seen as important for ensuring the quality of private auditors.[56]

III. The Enactment of the FSMA

1. The Process

Consumer advocates, including members of Congress, had been pushing for food safety legislation reform for over 20 years by the time the FSMA was enacted. A series of high-profile incidents, including the outbreak of E. coli in spinach and the recalls of peanut butter and eggs[57] and many others,[58] as well as an incident involving melamine in products from China in 2007,[59] created the perception of a food safety problem and deteriorating consumer confidence in food companies.[60] At the same time, consumer groups, industry, and the FDA all worked to develop policy white papers on what legislative reform was needed.[61]

Following the melamine outbreak, a federal policy window began to crack open as a series of Congressional hearings beginning in 2007 revealed that the FDA was overwhelmed, under-resourced, and lacked authority to react and respond to an increasingly complex and globalized food system.[62] In 2009, following the election of a Democratic Congress and President, momentum for the legislation accelerated with a bill moving through the House of Representatives rather quickly. Recognizing that a critical opportunity was emerging to change federal food safety policy, the Pew Charitable Trusts invested significant resources in consumer groups' advocacy efforts. Meanwhile the Grocery Manufacturers Association hired a key lobbyist – Scott Faber – whose experience and relations on Capitol Hill, as well as history working for the Environmental Working Group, made him a strong, trustworthy advocate for the bill.[63]

Despite the momentum, the bill stalled in the Senate while Democrats worked to push through universal healthcare finance reform legislation. The senate version of the bill was not taken up until late 2010 near the end of the Congressional session, when it had to compete with many other hot button issues such as "the Dream Act" and "Don't Ask, Don't Tell".[64]

55 *GFSI Guidance Document*, 6th ed. (The Global Food Safety Initiative, 2011).

56 Lytton And Mcallister "Oversight In Private Food Safety Auditing", *supra* note 21.

57 Discussed *supra* section II.1.

58 See Dewaal and Plunkett, "Building a Modern Food Safety System", *supra* note 32, at p. 2 for a list of other outbreaks.

59 See Patricia Sullivan, "Another Pet Food Ingredient is Contaminated by Chemical", 20 April 2007, at p. A8, Gardiner Harris and Andrew Martin, "U.S. Blocks Products with Milk from China", New York Times, 14 November 2008, at p. A18.

60 See, e.g., Peter D. Hart Research Associates and Public Opinion Strategies, "Results Of A National Survey On Produce Safety", Rory Harrington, "Bill bids to strengthen 'dangerous' US food safety regimes", Jenny McTaggart, "Food Safety: Safety Dance" *supra* note 19.

61 See Smith-DeWaal and Plunkett, "Building a Modern Food Safety System", "Food Protection Plan", "A Commitment to Consumers to Ensure the Safety of Imported Foods " *supra* note 32. The FDA specifically created the position of Association Commissioner of Food Protection and appointed David Acheson to conduct an internal assessment what resources and authorities FDA would need to more effectively govern food safety. FDA News Release, "FDA Commissioner Announces New Food Safety Protection Position," 1 May 2007, available on the internet at: http://www.fda.gov/newsevents/newsroom/pressannouncements/2007/ucm108903.htm (last accessed on 07 January 2015).

62 See, e.g., *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?", Hearing before H. Comm. on Energy and Commerce*, 111th Congress (2010).

63 According to one interview, "GMA also brought on a lobbyist who had good relations with the consumer groups, and that was Scott Faber. Scott's very effective lobbyist, very good, very knowledgeable, and strong personality with good relations on the hill, but at the same time he had a very good reputation with our groups because he came out of the environmental working group."

64 See Bill Marler, "FSMA: The End of My 20-Year Law Practice? Let's Hope So!", 19 March 2014, available on the Internet at: http://www.marlerblog.com/case-news/fsma-the-end-of-my-20-year-law-practice-lets-hope-so/#.u1a7r_ldwgc (last accessed on 17 April 2014).

Because of the November 2010 elections, control of the House would switch to Republicans in 2011, so it was believed that if legislation was not passed under the 111th Congress, it would not happen.[65] Though there had been general, well developed consensus among industry, academics, legislators and consumer groups in the early stages of the enactment, this delay was critical. Alternative food systems advocates allied with a cohort of sympathetic Senators to threaten blockage of the entire bill if their concerns were not addressed. This group was able to extract exemptions that were opposed by FDA, industry, and consumer groups.[66] Had there been more time, and had these groups been more engaged in other venues and phases of the policy development process, it is conceivable that a more palatable compromise of scaled regulation or technical assistance would have received more traction as a policy alternative.

In the end, the bill was passed so late in the legislative session that there was no opportunity to resolve differences between the Senate and House bills, leading to a wholesale adoption of the Senate bill as written.[67] Consequently, the exemptions for small scale producers were included, while provisions such as fees to fund implementation of the bill were not.

2. Final Provisions in the Law

The FSMA makes three significant changes to FDA authority: the FSMA requires FDA to develop a preventive food safety system; it enhances FDA inspection, compliance, and recall authority; and the legislation authorizes FDA to increase oversight of importers and their foreign suppliers through an audit and certification scheme.[68] The law does not contain provisions for funding the bill, which has potential implications for FDA's role and ability to implement the law.

a. Prevention

There are two key components to increasing prevention. First, FDA must develop Hazard Analysis and Risk-Based Preventive Controls (HARPC) for food processing facilities.[69] The law does, however, direct the agency to review preventive control programs such as HACCP that already exist, to ensure that the HARPC regulations are at least consistent with standards that are already in use."[70] Canons of legal interpretation of this language may require FDA to develop a program that relies on HACCP but is distinct from it.

Second, the agency must develop standards for the growing and handling of fresh produce.[71] Although FDA had previously worked with some commodities to develop guidance on preventing bacterial contamination,[72] this is a significant new authority and substantially broader area of regulation for FDA. Though USDA-operated GAP programs continue to exist as an available voluntary certification program, ultimate authority for evaluating compliance with public food safety standards has been assigned to the FDA.

As a result of the campaigns by alternative food systems advocates, there are limited exemptions to these requirements for small scale farms and manufacturers who primarily market through direct, local sales.[73] Though FDA retains authority to inspect and sanction these entities in the event of an outbreak,[74] it is expected that the states will generally oversee these smaller, exempt growers and manufacturers under state-level food safety laws. Buyers, including retailers and institutions such as schools and hospi-

65 See Marler, "Once GOP is in Kitchen", *supra* note 38.

66 Helena Bottemiller, "Food and Ag Groups Rally Against Tester Amendment", Food Safety News, 16 November 2010.

67 Bill Marler, "FSMA: The End of My 20-Year Law Practice? Let's Hope So!", *supra* note 64.

68 Food and Drug Administration, "Background on the Food Safety Modernization Act (FSMA)", available on the Internet at: http://www.fda.gov/food/guidanceregulation/fsma/ucm239907.htm (last accessed on 12 October 2014). For a more in depth discussion of the key provisions, and discretion left to FDA for fleshing out the rules, see Kristin Eads and Jennifer Zwagerman, "In Focus: Examining The New FDA Food Safety Modernization Act" 33 Hamline Journal of Public Law and Policy (2011) , pp. 123 *et sqq.*; Debra Strauss, "An Analysis Of The FDA Food Safety Modernization Act: Protection For Consumers And Boon For Business" 66 Food And Drug Law Journal (2011), pp. 353 *et. sqq*.

69 FSMA, *supra* note 7, § 103 (to be codified at 21 U.S.C. § 350(G)).

70 FSMA, *supra* note 7, § 103(N)(5).

71 FSMA, *supra* note 7, § 105 (to be codified at 21 U.S.C. § 350(H)).

72 See FDA, "FDA Issues Draft Guidances for Tomatoes, Leafy Greens and Melons", available on the Internet at: <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm174639.htm> (last accessed on 12 October 2014).

73 See National Sustainable Agriculture Coalition, "Food Safety Action Alert", 10 November 2010, available on the Internet at: <http://sustainableagriculture.net/blog/food-safety-action-alert-2/> (last accessed on 12 October 2014), National Sustainable Agriculture Coalition, "Senate Passes Food Safety Modernization Act", 30 November 2010, available on the Internet at: <http://sustainableagriculture.net/blog/senate-passes-food-safety-bill/> (last accessed on 12 October 2014).

74 See Kelly Damewood, "FSMA's Small Farm Exemption Has Its Limits", Food Safety News, 17 December 2013.

tals, are also likely to require certification to the standards, despite the exemptions.[75] FDA has historically relied on states to carry out significant portions of their inspections, and FDA has been criticized for failing to oversee the quality of states' programs. This calls into question the extent to which FDA's reliance on other entities will be effective.[76]

b. Inspection and Recall Authority

Under the FSMA, FDA has been given authority to inspect records,[77] mandate recalls[78] and withdraw a facility's registration.[79] Previously, the agency could only request that companies issue recalls (which companies for the most part did) or had to pursue a court order to mandate one. As a result FDA inspections had to be focused on building a court case and could not always be carried out in a manner that achieved immediate corrections. Under FSMA, the agency can threaten to withdraw a registration in order to secure compliance with the law. Indeed, the agency has used the threat and actual suspension of registration to deal with problematic companies.[80] The agency has also increased its use of judicial enforcement, bringing criminal prosecutions against the Peanut Corporation of American executives for the 2008 peanut butter recall and the owners of a cantaloupe farm that caused the most deadly foodborne illness outbreak of the last 30 years in the summer following enactment of the FSMA.[81]

c. Third Party Verifications

The third major component of the legislation pertains to imported foods.[82] The law requires importers to verify that their suppliers are in compliance with the US food safety system, and authorizes FDA to establish programs requiring certifications for certain foods[83] and recognizing third party audits.[84] These provisions impose significant responsibility on private importers and auditors – rather than the FDA – to detect and prevent contamination of imported foods. Imports make up an increasing proportion of the US food supply, so this allocation of authority establishes in public law a significant role for the private sector in policing and ensuring food safety.

d. Funding

A final important component of the law pertains to funding. During deliberations, how to fund the bill was a significant issue of concern. The House version had included facilities' registration fees while the Senate version did not. It was expected the fees would be included in a final version when the bill was finalized by a joint conference committee of the House and Senate.[85] Due to the delay in enacting the Senate bill, the final law included no provisions to guarantee funding for FDA's increased activities. Consequently, FDA must annually request (and justify) a budget as part of the appropriations process.

IV. Implications

As a historic revision of US food safety legislation,[86] the law grants the FDA broad new powers. Yet closer examination reveals that, though some significant changes occur, in many ways the law repeats or fails to address past public regulatory failures, and does

75 See Food and Drug Administration, "FDA Answers Farmers' Questions: Answers to Questions about the Original FSMA Produce Safety Proposed Rule from Mike Taylor, Deputy Commissioner for Foods and Veterinary Medicine", available on the Internet at: <http://www.fda.gov/food/guidanceregulation/fsma/ucm358090.htm> (last accessed on 17 October 2014).

76 See "FDA Oversight Of State Food Inspection Programs: A Call For Greater Accountability", OEI-01-98-00400 (Department of Health and Human Services, Office of Inspector General, June 2000), "Vulnerabilities In FDA's Oversight Of State Food Facility Inspections", OEI-02-09-00430, (Department of Health and Human Services, Office of Inspector General, December 2011), Dewaal and Plunkett, "Building A Modern Food Safety" *supra* note 32.

77 FSMA, *supra* note 7, § 101 (To Be Codified at 21 U.S.C. 350c(A))).

78 FSMA, *supra* note 7, § 206 (To Be Codified At 21 U.S.C. 341 Et Seq.).

79 FSMA, *supra* note 7, § 102(B) (To Be Codified at 21 U.S.C. 350d(A))).

80 See Ted Agres, "'Doing the Right Thing' to Ensure Food Safety: Incorporate Food Safety into all Aspects of Your Business or Risk Becoming a Target of FDA's New Enforcement Powers", Food Quality and Safety Magazine, June/July 2014. See also Acheson, "FDA FSMA Facility Suspension Power", *supra* note 41.

81 See Jessica Dye, "Experts Predict More Criminal Scrutiny for Food Safety in 2014", Reuters Legal, 26 December 2013.

82 FSMA, *supra* note 7, § 301 *et sqq*.

83 FSMA, *supra* note 7, § 303

84 FSMA, *supra* note 7, § 307

85 See Helena Bottemiller, "Senate Holds Hearing on Food Safety Reform", Food Safety News, 23 October 2009, stating "many experts expect that the house's fee provision will survive conference if the senate does not add a fee provision to help fund the bill, but it is an issue that will be watched very closely."

86 Helena Bottemiller, "Historic Food Safety Bill Signed Into Law", Food Safety News, 5 January 2011.

not fundamentally restructure the roles and relationships between actors in the broader food safety governance network. Disaggregating and closely examining the various actors in the context of the FSMA shows how the law changes the roles and relationships between regulators, the regulated industry, and other stakeholders.

1. Government

a. Hybridizing Authorities

The FSMA gives FDA power to mandate new food safety standards and an expanded toolkit for enforcing them. Yet the HACCP-like preventive controls and new import programs also assign significant new responsibility to manufacturers, importers and auditors for ensuring food safety. Additionally, the limited funding and small-scale exemptions will necessitate relying on states to carry out inspections and assist in outbreak investigations.

The FDA has historically contracted with states to carry out significant portions of inspection and oversight of facilities, as well as coordinating on development and adoption of the Food Code. Though altered, the FSMA does not profoundly restructure the relationships between Federal and State agencies. The new role for importers and third party auditors is, however, a significant new relationship that will require the FDA to develop effective systems for coordinating with these actors.

Hybridization of public and private regulation has occurred in other countries[87] and industries.[88] This parallels broader processes in governance, where public agents are increasingly expected to manage complex networks in order to achieve government objectives and deliver services.[89] In addition to understanding and enforcing food safety best practices, the FDA must now develop expertise in understanding auditing practices and develop strategies for coordinating and partnering with private auditors and importers for the effective oversight of imported foods.

This is potentially problematic, given that the coordination and oversight of states by FDA has been criticized as ineffectual[90] and the Government Accountability Office has recently called for improving overall coordination of food safety systems.[91] Further, the states' role under FSMA occurs at a time when states inspection capacities are being reduced by funding cuts[92] and no money is being provided to assist importers or third party auditors. This means the FDA has a daunting task.

b. Hampered by Lack of Funding and Expertise

Interviews with produce industry and food manufacturers also raised concerns that FDA has limited experience regarding the realities of the production processes and business practices that ensure the safety of products. Industry had been developing and extensively implementing standards for production and processing of food. The agency has experience with these systems, through work it has done developing HACCP programs for juice[93] and seafood[94] and GAP guides for the produce industry. However, the FSMA imposes responsibility to regulate a far broader and more diverse set of products within a single cohesive set of regulations. Given FDA's limited experience with only single-product regulations, it is a significant challenge for the agency to develop and implement a set of regulations that are general enough to apply to all foods, yet not so vague that they will be inconsistently enforced.

These challenges are further complicated by Congress's failure to fund the bill through facilities fees. Rather than be able to rely on a secure source of funding for operations, the agency must pursue funding through the normal appropriations process. So that as the agency attempts to write and enforce the reg-

87 See, e.g., Marian Garcia Martinez et al., "Co-regulation as a possible model for food safety governance: Opportunities for public–private partnerships," 32 *Food Policy* (2007), 299 *et sqq.*, Paul Verbruggen and Tetty Havinga, "Food Safety Meta-controls in the Netherlands", in this Special Issue.

88 For example, forestry has seen the emergence of private standard that are increasingly mandatory due to public adoption of the standards. Errol Meidinger, "The Administrative Law of Global Private-Public Regulation: the Case of Forestry," 17 *European Journal of International Law* (2006) 47 *et sqq*.

89 Eva Sorensen and Jacob Torfing, "Making governance networks effective and democratic through metagovernance," 87 *Public Administration* (2009) 234 *et sqq*.

90 See OIG oversight reports, *supra* note 75.

91 Government Accountability Office, Federal Food Safety Oversight: Additional Actions needed to improve planning and collaboration, GAO-15-180, Dec. 2014.

92 http://www.foodquality.com/details/article/6166181/Staffing_Reductions_Curtail_Prevention_Investigation_of_Foodborne_Illness_Outbre.html

93 21 C.F.R. § 120.1 (2014)

94 21 C.F.R. § 123.6 (2014)

ulations, stakeholders retain a key leverage point for holding the agency accountable for actions stakeholders' are unhappy with.[95]

c. Implications for FDA

Between the partnering mandates, lack of funding, and lack of expertise, this is a law that FDA cannot implement unilaterally. The agency needs other members of the food safety governance network to subscribe to the agency's coordinating efforts. The FDA has been repositioned as a network manager that attempts to coordinate a dispersed network of actors with variable powers and expertise. Through its clout as a federal agency, the FDA retains significant power to regulate, but that power is now exercised through a more dispersed and collaborative set of relationships with other regulators, regulated entities and stakeholders.

Scholars have argued for the promise of positioning regulatory agencies as co-regulators and harnessing the power private regulation.[96] Under the FSMA, the FDA is severely resource constrained and subject to traditional administrative law mechanisms designed to hold the agency accountable to stakeholders.[97] Added to this is the agency's historically ineffective coordination of the simpler network of federal and state regulators. The FSMA clearly puts a strain on FDA's expertise and capacity to act as network coordinators, and the agency's success in its new role will necessitate careful future assessment from a variety of angles.[98]

2. Industry

This examination of the FSMA also necessitates examination of how public regulation may be reshaping private regulations.[99] For industry on the whole, the provisions of the law does alter some actors' roles and responsibilities in the governance of food safety, particularly relative to the FDA. However, the law leaves in-tact portions of the private regulatory regime so that, in some ways, there is little change in the relative authorities and responsibilities within industry. While the law adds responsibilities for many smaller and midsized producers, for those selling to major retailers, the law only minimally changes the obligations relative to private standards. Nor do any provisions redistribute the power of retailers and buyers, so that anyone wishing to sell to these buyers must still comply with stringent food safety standards that exceed the floor established by the FSMA.

a. Food Producers

For food producers, the new provisions have varied effects depending on their previous roles. Many growers and manufacturers already are subject to private governance regimes that impose stringent food safety standards and auditing requirements, such as the GFSI benchmarked schemes for retailers and the LGMA standards for California and Arizona leafy greens growers. For these producers, the implications of the changes will depend in large part how much the FDA's rules diverge from current industry practices. The adoption of HARPC, rather than HACCP, means that US food safety regulations could in some ways diverge from global standards. On the whole, industry informants expected this divergence from globally accepted terminology and practices to make compliance more complex for globalized food companies and complicate FDA's efforts at enforcement when dealing with companies in foreign countries. If this occurs, the law has the potential to simply add to the regulatory universe, and may not help achieve resolution and harmonization to address the issues of conflict and rule-proliferation that these producers already face.

95 See e.g. *Examining the Implementation of the Food Safety Modernization Act, before the H. Comm. on Energy and Commerce, Subcomm. on Health*, 113th Congress (February 5, 2014).

96 Tacy Katherine Hass, "New Governance: Can User-Promulgated Certification Schemes Provides Safer, Higher Quality Food?", 68 *Food and Drug Law Journal* (2013) 77 *et sqq.*; Jason Solomon, "New governance, preemptive self-regulation, and the blurring of boundaries in regulatory theory and practice," *Wisconsin Law Review* (2010) 591 *et sqq.*; Lesley K. McAllister, "Harnessing Private Regulation," *U-C Davis Legal Studies Research Paper* (2013).

97 For instance, the agency must conduct rulemaking through the traditional "ossified" notice and comment process, rather a more flexible process such as negotiated rulemaking whereby the agency convenes the stakeholder groups to negotiate a set of rules. Jody Freeman, "Collaborative governance in the administrative state," 45 *UCLA Law Revew* (1997) 1 *et sqq.*.

98 See, e.g., Sorensen and Torfing, *supra* note 89; Erik-Hans Klijn, Bram Steijn & Jurian Edelenbos, "The impact of network management on outcomes in governance networks", 88 *Public Administration* (2010) for discussions of how network managers might be evaluated.

99 Lars H. Gulbrandsen, "Dynamic governance interactions: Evolutionary effects of state responses to non-state certification programs," 8 *Regulation & Governance* (2014) 74 *et sqq.*

For many others, these are significant new requirements that, while bringing them up to speed with what others in the industry have been doing, will require significant education and investment in production processes.[100] The FDA initiated coordinated education with academics, states, and industry to reach this segment and ensure they understand and are in compliance with the new requirements. Most prominently, FDA has funded the Produce Safety Alliance and the Preventive Controls Alliance to develop and deliver educational curriculums. The funding of these education efforts represents another example of how the complex governance networks are imposing an increased stakeholder coordination role on the FDA.

b. Exempt Producers

There are, in addition, a set of exempt producers and manufacturers. Despite a hard fought battle to have certain farms and small food manufacturers exempt from FDA's standards, one concern that has been raised by some advocates is that the marketplace will nonetheless impose private or public standards on small producers and force them to incur the high costs of audits if they want to access mid or large scale markets. This suggests that the power of retailers and buyers essentially moots out the power of the federal government to create "scale appropriate" regulation. Though federal regulations may override private regulation, private regulation can also preclude federal policy efforts, putting the two regulatory systems in a rather heterarchical status relationship vis-à-vis one another. This pattern of private regulation precluding or preempting public regulation is not remarkably new.

c. Buyers

The implementation of the FSMA also resurrects a recurring discussion regarding who is ultimately responsible for food safety. As mentioned above, US retailers have relatively limited liability in the event of a food safety outbreak. However, they are often in the most powerful position to enforce (or undermine) food safety practices because their purchasing decisions affect the extent to which producers can and will invest in food safety. This issue has generated industry discussions of whether food safety is the responsibility of individual producers, or if retailers and major buyers must change their buying practices, or if universal, public regulation would solve food safety failures.[101] Currently, the FSMA puts responsibility on food producers and assigns enforcement authority to FDA, states, and importers, leaving retailers relatively unaccountable for ensuring food safety.

d. Third Party Auditors

Many audits are carried out by third party auditors because they are ostensibly independent and conflict-of-interest free. However, scholars have questioned the true independence of these audits[102] and many companies choose to use internal auditors for evaluating suppliers rather than or in addition to relying on third parties. The issue is one of accountability – as Busch asks, "Who will guard the guards?"[103] For imported foods, the answer is now that FDA will take on the role of guarding the guards. For domestic production, private auditors will remain subject to the systems of private accreditation and oversight that preceded the FSMA. This partial adoption of the private inspection system in a limited way recognizes the potential legitimacy of private actors as inspectors and regulators, so long as they remain subject to systems of government oversight.

3. Civil Society

Remarkably, despite civil society's significant role in the enactment of the FSMA, the analysis does not suggest there has been a radical restructuring of roles. Clearly the consumer groups influenced the bill, but their power was limited until industry was willing to

100 The importance of education for successful implementation of self-regulatory programs is key. Martinez et al., *supra* note 87 at 308.

101 See Discussion, *Supra* Section II.1. See also Jim Prevor, "Buyer Led Food Safety Initiative Recap", *supra* note 18, Jim Prevor, "The Cantaloupe Crisis: The Truth That Dare Not Speak Its Name: The Priority can be Safe or the Priority can be Local, but it cannot be Both", Perishable Pundit, available on the Internet at: <http://www.perishablepundit.com/index.php?date=10/04/2011&pundit=1> (last accessed on 13 October 2014).

102 Scholars have questioned this independence. See Maki Hatanaka And Lawrence Busch, "Third-Party Certification In The Global Agrifood System: An Objective Or Socially Mediated Governance Mechanism?" 48 *Sociologia Ruralis* (2008) , pp. 73 *et sqq*.

103 Lawrence Busch & Carmen Bain, "New! Improved? The Transformation of the Global Agrifood System," 69 *Rural Sociology* (2004) 321 *et sqq*.

support and work with consumer groups on the legislation. While the battle over exemptions revealed a fracture between the food advocacy civil society organizations that one might expect have common interests, it is also normal for civil society movements to have internal conflicts and rifts.[104] The possible importance here is that the FSMA battles highlighted the importance of including the alternative groups. Though sustainable and alternative organizations have had past policy advocacy successes, several interviews noted that the FSMA conflicts significantly elevated these organizations status as a legitimate and distinct perspective.

V. Conclusions

Private regulatory regimes in the United States emerged to fill in gaps and breakdowns that were resulting from an ineffectual domestic regulatory agency and to manage the risks in global food supply chains. This is not to say government agencies were absent; the FDA did what it could under the FDCA while other state and federal agencies were partnering with various sectors to govern food safety. However the plurality of policies was forcing producers and manufacturers to comply with multiple, stringent standards that were becoming increasingly costly and difficult, and efforts to harmonize the regimes were largely ineffectual. At the same time, uneven adoption and enforcement failures were allowing frequent outbreaks to occur, creating a perception of eroding consumer trust in food companies and the US food supply.

In the late 2000s, consensus emerged among the major stakeholders that federal legislation would be beneficial. Following a typical pattern of the policy cycle, [105] it was not clear until the last possible moment that food safety legislation could outcompete other agenda items to successfully be passed, nor what provisions would be finally included. Consumer groups took advantage of the democratic House, Senate and President, combined with the ongoing outbreaks, to force open a policy window and bring food safety reform onto the Congressional agenda. The policy alternatives that were considered had been developed and tested by subsets of stakeholders in other venues, such as the LGMA and GFSI. As a result of the outcomes seen in those venues, stakeholders hotly contested how broadly regulations should apply and the appropriate roles of state and private regulators in overseeing and enforcing food safety.

Ultimately, what was produced was not necessarily a rational bill, but rather a series of compromises on previously tested policy alternatives that politically effective stakeholders agreed they could live with. The FSMA both expands FDA domestic and import authority and elevates the role of private regulators and industry. For FDA regulators, the law means trying to navigate a line between independence and collaboration, while being responsive to a variety of conflicted stakeholders. For industry trying to manage global systems, the law could help by setting a floor for all producers, but create increasing regulatory complexity. And for the private regulators, the legislation holds potential to increase their legitimacy as effective guards of food safety.

With the enactment of the FSMA, the United States has moved towards an increasingly integrated public-private regulatory system. The next phases, rulemaking and implementation, will constitute another venue of interactions. The outputs will clarify just what roles stakeholders might play and possibly shift the impacts of the different regulatory regimes. This may catalyze contests and policy cycles in multiple other venues, including potential court challenges to FDA's decisions, as well as shifts in GFSI schemes and rewriting of the USDA and state-level regulations and enforcement. With the shift to the increasingly complex networks of governance, on-going research will be needed into the dynamic and continuous processes that now shape food safety governance in the United States.

104 See, e.g., Robert Gottlieb, *Forcing the spring: The transformation of the American environmental movement* (Island Press: Washington DC, 2005) for a discussion of the diverse roots and conflicts that have played out in the environmental movement in the United States.

105 Kingdon, *Agendas, Alternatives and Public Policies*, *supra* note 13.